(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 August 2001 (16.08.2001)

PCT

(10) International Publication Number
WO 01/58522 A1

(51) International Patent Classification[7]: A61N 1/39

(21) International Application Number: PCT/US01/03810

(22) International Filing Date: 5 February 2001 (05.02.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/502,311 11 February 2000 (11.02.2000) US

(71) Applicant: **THERACARDIA, INC.** [US/US]; 1062-F Calle Negocio, San Clemente, CA 92673 (US).

(72) Inventors: **MASSON, Stephen, C.**; 13453 S.W. 58th Avenue, Miami, FL 33156 (US). **BUCKMAN, Robert, F.**; 125 Chew Lane, Radnor, PA 19087 (US). **LENKER, Jay, A.**; 408 Panorama Drive, Laguna Beach, CA 92651 (US). **BRENNEMAN, Rodney, A.**; 34002 Las Palmas Del Mar, San Juan Capistrano, CA 92675 (US). **LAWSON, Robert, A.**; 1588 Skyline Drive, Laguna Beach, CA 92651 (US).

(74) Agents: **HESLIN, James, M.** et al.; Townsend and Townsend and Crew LLP, 2 Embarcadero Center, 8th Floor, San Francisco, CA 94111 (US).

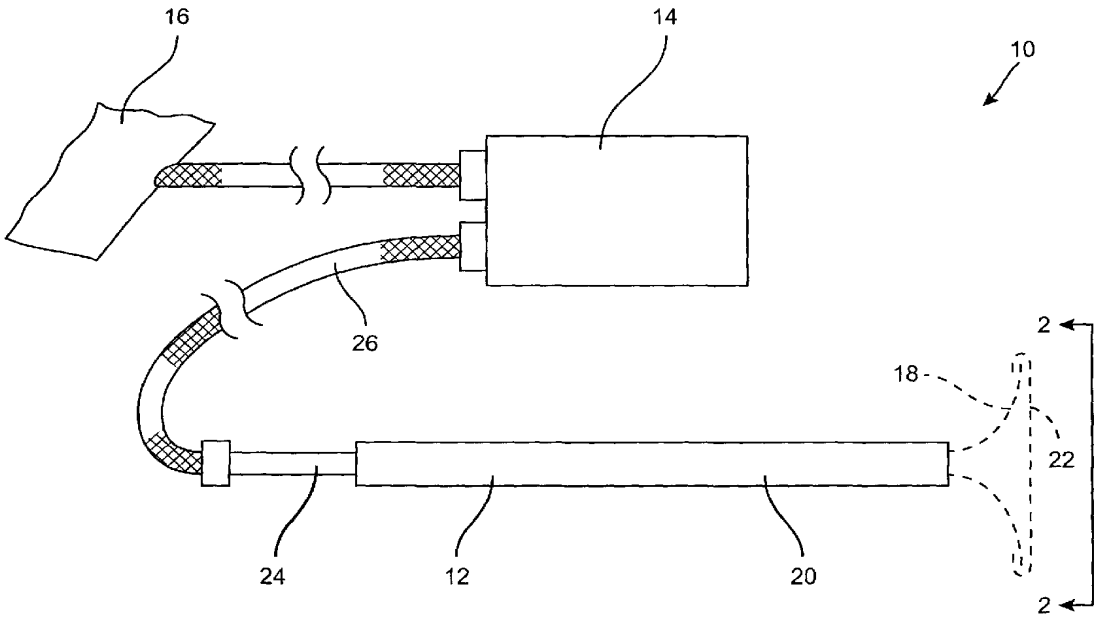
(81) Designated States *(national)*: AU, CA.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEMS AND METHODS FOR PERCUTANEOUS CARDIAC TREATMENT



(57) Abstract: Cardiac resuscitation systems (10) comprise a defibrillator (14) and a device which carries a deployable electrode structure (12) at the distal end of a support (20).

WO 01/58522 A1

SYSTEMS AND METHODS FOR PERCUTANEOUS CARDIAC TREATMENT

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is related to co-pending application no. 09/409,050, filed on September 27, 1999, the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to medical devices and methods. More particularly, the present invention relates to devices and methods for performing minimally invasive direct cardiac defibrillation, pacing, monitoring, and massage.

Sudden cardiac arrest is a leading cause of death in most industrial societies. While in many cases it is possible to re-establish cardiac function, irreversible damage to vital organs, particularly the brain and the heart itself, will usually occur prior to restoration of normal cardiac activity.

A number of techniques have been developed to provide artificial circulation of blood to oxygenate the heart and brain during the period between cardiac arrest and restoration of normal cardiac activity. Prior to the 1960's, open chest cardiac massage (OCM) was a standard treatment for sudden cardiac arrest. Open chest cardiac massage, as its name implies, involved opening a patient's chest and manually squeezing the heart to pump blood to the body. In the 1960's, closed chest cardiac massage (CCM) where the heart is externally compressed through the chest wall became the standard of treatment. When CCM is combined with airway support, it is known as cardiopulmonary resuscitation (CPR). CPR has the advantage that it is much less invasive than OCM and can be performed by less skilled individuals. It has the disadvantage, however, that it is not generally effective at pumping blood for more than a few minutes. In particular, the medical literature shows that CCM provides significantly less cardiac output, neuroperfusion, and cardiac perfusion than achieved with OCM.

Methods and devices for performing minimally invasive direct cardiac massage have been described by Buckman et al. and by Drs. Filiberto and Giorgio Zadini in the patent and literature publications listed in the Description of the Background Art below. While the methods of Buckman et al. and the Zadinis differ in a number of

respects, they generally rely on introducing a balloon, shoe, or other deployable member to engage the heart through a small incision through an intercostal space above the pericardium. The heart may then be pumped by directly engaging and compressing the pericardium, either by inflating and deflating the member or by reciprocating a shaft attached to the member. Improved devices for performing direct cardiac massage are described in copending, commonly assigned application nos. 09/087,665 and 09/344,440, the full disclosures of which are incorporated herein by reference. Data show that such devices are able to achieve significantly improved hemodynamic parameters when compared to conventional closed chest cardiac massage.

Patients in sudden cardiac arrest have various states of dysfunction including ventricular fibrillation, ventricular bradycardia, ventricular tachycardia, electromechanical dissociation, and asystole. Thus, to properly evaluate patients in sudden cardiac arrest, it is necessary to monitor electrical heart function by performing an electrocardiogram (ECG or EKG). Those patients found to be suffering from a heart arrhythmia might also be treated with direct current defibrillation to effect electrical cardioversion to a more stable heart rhythm.

Direct current defibrillation is performed using electrical countershock by placing defibrillating pads on the patient's chest. When ventricular fibrillation or other arrhythmia is observed, the patent is treated with a countershock typically in the range from 200 to 300 joules. If the initial countershock is unsuccessful, a second shock in the same energy range is given. If the arrhythmia persists, a third countershock at a higher energy level, typically about 360 joules, is used.

The availability of direct current defibrillation has enabled the saving of thousands of lives each year. It is effective in treating patients for whom no alternative therapies would be available. Despite such success, the need to use such high energy levels can itself cause injury to the patient. Many patients who have been successfully revived using defibrillation suffer damage to the electrical pathways in the heart and require pacemakers and/or internal cardiac defibrillators for the rest of their lives. Conversely, even the very high energy levels which are used in cardiac defibrillation are not effective for all patients. The significant electrical resistance and broad electrical dispersivity of the patient's chest greatly reduces the energy which is actually delivered to the heart tissue. Thus, a practical limit exists on the ability to deliver effective direct current defibrillation to the heart using external pads.

The use of internal electrodes for providing cardiac defibrillation has been proposed in a number of circumstances. As mentioned above, patients having chronic arrhythmias can now be treated with implanted, internal cardiac defibrillators which both sense an arrhythmia and deliver a countershock to correct the arrhythmia. Additionally, small electrical paddles (called "spoons") have been used in open surgical procedures for directly applying defibrillation energy to an exposed heart. Under such circumstances, defibrillation can be achieved with much lower energies than are required with closed chest defibrillation. Neither approach, however, is effective for treating patients in sudden cardiac arrest where the patient has neither an implanted defibrillator nor an exposed heart to permit direct cardiac defibrillation.

For these reasons, it would be desirable to provide improved methods, apparatus, and kits, for defibrillating patients in sudden cardiac arrest. In particular, it would be desirable to provide such improved methods and apparatus which enable and facilitate the simultaneous performance of cardiac defibrillation and/or pacing together with direct cardiac massage in such patients. It would be particularly desirable if the methods and apparatus could also provide for monitoring of the patient's heart rhythm during emergency resuscitation procedures and/or for providing other user feedback during such procedures. Additionally, it would be desirable to provide defibrillators, pacers, and/or monitors which are specially configured for use with percutaneously delivered cardiac electrodes rather than external electrodes. For example, it would be desirable if the percutaneous defibrillators provided for improved synchronization between (1) defibrillation and/or pacing, and (2) direct cardiac compression using devices which carry the cardiac electrodes. The defibrillators and defibrillator systems could also provide for improved operation and safety when used for direct cardiac defibrillation, and the defibrillators themselves could have a reduced size made possible because of the lower energy requirements of direct cardiac defibrillation. In some cases, it will be desirable to provide percutaneous cardiac compression devices having self-contained power and circuitry for performing defibrillation and/or pacing on patients. It would still further be useful if the "defibrillators" were configured so that they could be used for other functions, such as pacing and cardiac monitoring, either with or without actual defibrillation of the patient. At least some of these objectives will be met by the inventions described hereinafter.

2. Description of the Background Art

U.S. Patent Nos. 5,582,580; 5,571,074 and 5,484,391 to Buckman, Jr. et al. and 5,683,364 and copending application no. 09/287,230 to Zadini et al., licensed to the assignee of the present application, describe devices and methods for minimally invasive direct cardiac massage through an intercostal space, which optionally incorporate electrodes for defibrillation, pacing, ECG monitoring, and cardioversion. Published PCT application WO 98/05289 and U.S. Patent Nos. 5,466,221 and 5,385,528 describe an inflatable and other devices for performing direct cardiac massage. U.S. Patent No. 3,496,932 describes a sharpened stylet for introducing a cardiac massage device to a space between the sternum and the heart. Cardiac assist devices employing inflatable cuffs and other mechanisms are described in U.S. Patent Nos. 5,256,132; 5,169,381; 4,731,076; 4,690,134; 4,536,893; 4,192,293; 4,048,990; 3,613,672; 3,455,298; and 2,826,193. Dissectors employing inflatable components are described in U.S. Patent Nos. 5,730,756; 5,730,748; 5,716,325; 5,707,390; 5,702,417; 5,702,416; 5,694,951; 5,690,668; 5,685,826; 5,667,520; 5,667,479; 5,653,726; 5,624,381; 5,618,287; 5,607,443; 5,601,590; 5,601,589; 5,601,581; 5,593,418; 5,573,517; 5,540,711; 5,514,153; and 5,496,345. Use of a direct cardiac massage device of the type shown in the Buckman, Jr. et al. patents is described in Buckman et al. (1997) Resuscitation 34:247-253 and (1995) Resuscitation 29:237-248. External and internal defibrillators and defibrillation waveforms are described in U.S. Patent Nos. 5,913,877; 5,908,442; 5,899,924; 5,833,712; 5,824,017; 5,725,560; 5,634,938; 5,605,158; 5,591,209; 5,514,160; 5,447,518; 5,413,591; 5,411,525; 5,184,616; 5,083,562; and 5,014,701.

SUMMARY OF THE INVENTION

The present invention provides improved methods, systems, apparatus, and kits for resuscitating patients in cardiac arrest, including patients suffering from ventricular fibrillation (VF), ventricular tachycardia (VT), cardiac arrhythmias, cardiac asystole, pulseless electromechanical activity (PEA), and the like. The present invention is particularly useful for combining direct cardiac compression therapy with cardiac electrical therapies, such as defibrillation, pacing, and cardioversion, as well as ECG/EKG monitoring of the heart. The present invention is particularly advantageous since it allows great flexibility in treating patients depending on the exact nature and course of their cardiac failure. While the prior art recognizes the desirability of combining direct cardiac massage with defibrillation, pacing, cardioversion, and/or

monitoring, the devices, defibrillators, and other system components described for performance of such combined therapies are far from optimized. At best, the prior art teaches that relatively simple electrode structures can be provided on a direct cardiac massage device or that electrodes which are not optimized for performing direct cardiac massage may be utilized for defibrillation. Very little information is given on how conventional defibrillators, pacing systems, etc., should be modified for optimal use with direct cardiac contact electrodes. In particular, little guidance is given with respect to useful defibrillation energies, approaches for synchronizing defibrillation with other therapies, defibrillation designs, or the like. The present invention provides a number of specific improvements for the methods, systems, and apparatus used for the minimally invasive defibrillation, monitoring, and pacing, of patients in sudden cardiac arrest. The present invention still further provides apparatus and kits which are optimized for performing such methods, particularly where the devices may also be used for direct cardiac compression.

In a first aspect of the present invention, methods and apparatus are provided for defibrillating a patient's heart. The methods and apparatus are especially adapted for use with "percutaneous" defibrillation protocols where an electrode structure is percutaneously introduced, usually through an intercostal access hole, and contacted against the heart or pericardium. Defibrillation energy is then applied to the heart or pericardium through the electrode structure, usually in combination with a counter electrode which is placed externally on the patient, typically on the patient's back beneath the heart or near the patient's right shoulder. Such percutaneous defibrillation will require defibrillation energies which are generally less than those associated with external defibrillation, i.e., defibrillation where pairs of electrode pads or paddles are placed on the patient's chest, and generally more than those required for internal defibrillation using either spoons or implantable cardiac defibrillators (ICD's). Percutaneous defibrillation may require an energy in the range from as low as 0.1 joule to a maximum of 120 joules. Applying defibrillation energy above 120 joules would likely present an unacceptable risk of damaging the heart. Thus, the methods and systems of the present invention will generally provide for a defibrillation energy limit at 120 joules, preferably at 100 joules, and often at 80 joules. The methods and defibrillation systems will usually operate in a range from 0.1 joule to 100 joules, preferably from 1 joules to 70 joules, more preferably from 10 joules to 60 joules, when the applied waveform is biphasic. Optionally, the defibrillator may be prevented from delivering energy outside any of the above ranges.

In a preferred aspect of the defibrillation methods, the energy may be applied automatically to the patient at successively higher levels until the defibrillation threshold is achieved or the maximum energy level, e.g., 120 joules, is reached. Usually, the defibrillation energy is first delivered at a relatively low level, typically from 0.1 joule to 30 joules, and then the patient checked to see if defibrillation (normal sinus rhythm) has been achieved. If not, the defibrillation energy is then increased at a higher level, typically from 10 joules to 20 joules above the preceding step. The patient is then again checked if normal sinus rhythm has been achieved. If not, an additional treatment step will be performed. Such treatment and evaluation steps will be continued until the normal heart rhythm is achieved or maximum treatment energy is reached.

In addition to the methods just described, the present invention will comprise computer programs in a tangible medium setting forth such methods. The tangible medium may comprise volatile or non-volatile memory within the defibrillator, may comprise programming within an external computer which is linked to the defibrillator, or may be present in any other conventional form of digital data storage, e.g., floppy disks, optical disks, etc.

In a second aspect of the present invention, patients in asystole are resuscitated by contacting an electrode structure against the heart or pericardium. Instead of applying defibrillation energy (as would be used for patients in ventricular fibrillation), pacing energy will be applied to the heart or pericardium through the electrode structure. Typically, pacing energy is very low when compared to defibrillation energy, typically being in the range from 5 mA to 200 mA, usually from 10 mA to 100 mA, and the pacing signal is repeated in a rhythmic pattern corresponding to a desired heartbeat, typically at from 40 pulses/minute to 120 pulses/minute, usually from 50 pulses/minute to 80 pulses/minute. When heartbeat is reestablished, the pacing can be discontinued and, optionally, a permanent pacer implanted.

Optionally, such pacing methods of the present invention for the treatment of asystole or other conditions will be combined with direct cardiac compression. Usually, direct cardiac compression will be performed with the electrode structure, which thus also acts as a cardiac compression structure. In the most preferred case, the pacing energy and the direct cardiac compression will be performed synchronously or with a phase lag. Such synchronous compression and pacing can be achieved in a variety of ways. For example, the pacing signal could be triggered by movement of the cardiac compression device. In such case, the user would set the pacing rhythm based on manual

(or possibly machine powered) heart compression. Alternatively, the pacing signal could be fixed by the system electronics with a visual or audible signal being provided to the user. In the latter case, the user would then attempt to synchronize the compression motions to the visible or audible signal. In some cases, of course, it will be possible to provide fully automated systems where both the direct cardiac compression and the pacing are controlled and synchronized via system electronics and/or mechanical drivers.

Further optionally, the electrode array and system electronics could be configured to pace different parts of the heart in different ways, i.e., the pacing signals need not be applied over the entire cardiac contact surface area or during the entire course of treatment in a uniform or consistent manner. For example, the electrodes and systems could be configured to deliver different energy levels to different regions of the cardiac surface. For example, the atrial and ventricular regions of the heart may be separately paced in the case of a conduction bundle block at the atrioventricular node. Alternatively, the electrodes and electronics can be configured to sequentially deliver phased electrical pulses over the cardiac surface in order to simulate or mimic the lateral electrical wave patterns that occur in the heart during normal sinus rhythm. In the latter case, the electrode structure can include a plurality of isolated regions which are configured and oriented to mimic the natural electrical stimulation pattern of the heart. In that case, the electrode structure will usually require a predetermined orientation relative to the heart before applying the pacing signals. Particular electrode structure designs which permit such orientation are described hereinafter. Alternatively, the electrode structure could include a symmetric array of relatively small isolated regions. In the latter case, it would be possible to have the array initially sense its orientation relative to heart and have the system electronics then adjust the pattern of electrical signal delivery accordingly.

In a third aspect of the present invention, patients in asystole or bradycardia are resuscitated by percutaneously introducing a compression structure to a region over the heart. The compression structure is used to compress the heart, typically by manual compression, and pacing energy is applied to the heart synchronously with the direct cardiac compression. While the pacing energy will typically be provided through an electrode structure on the compression structure, it will also be possible to apply pacing externally to the patient, e.g., through the use of external pads. Pacing and cardiac compression can be synchronized by any of the methods described previously.

In a fourth aspect of the present invention, methods for resuscitating a patient in cardiac failure rely on use of a percutaneous cardiac compression device. The

nature of the cardiac failure is initially determined from among at least asystole, ventricular fibrillation, pulseless electromechanical activity (PEA), and optionally ventricular tachycardia. The cardiac compression device is percutaneously introduced to a region over the heart, usually through an intercostal space, and the device is engaged against the heart, pericardium, or other cardiac surface. The heart is then compressed in a rhythmic fashion in order to induce blood circulation. In addition to the cardiac compression, further intervention is performed depending on the nature of the cardiac failure. Monitoring of the EKG/ECG can provide sufficient information to allow diagnosis of the nature of the cardiac failure. Depending on the diagnosis, a particular treatment course can be recommended, (e.g., by display or monitor on the system) or may be automatically initiated. If the patient is determined to be in asystole, pacing energy will usually be direct to the heart, preferably through an electrode present on a surface of the compression device. In some cases, however, it may be unnecessary to provide pacing energy since the heart may return to a normal cardiac rhythm without pacing. The ability to distinguish among patients requiring defibrillation from those who require only pacing or possibly no electrical treatment whatsoever is a particular advantage of the present invention. Even with the reduced energy levels employed with direct cardiac defibrillation as described herein, there is still a risk of injury to the patient, such as conduction bundle block caused by an applied high potential on the heart. Such risk is avoided if it can be determined that a patient does not need defibrillation treatment at the outset. If the patient is determined to be in ventricular fibrillation of sufficient strength (e.g., above 0.1 mv amplitude or polymorphic without diastolic plateaus), defibrillation energy will be applied to the heart. While such energy could be applied using external pads or electrode structures, the method of the present invention preferably relies on delivering the defibrillation energy through an electrode surface on the compression device. If the patient is determined to be in PEA, then usually no defibrillation or pacing will be performed. Patients in PEA may be advantageously treated by direct cardiac compression timed to follow the natural electrical signals of the heart or by secondary external electrodes. The systems and methods of the present invention allow determination of EKG/ECG using the electrodes which are in contact with the heart. The system electronics can then provide a pacing signal which the practitioner can use to manually or automatically time the heart compressions being applied. Optionally, patients suffering from ventricular tachycardia may also be identified in the initial determination step. Patients determined to be in ventricular tachycardia, will preferably

be treated with electrical pacing, usually applied through an electrode on the cardiac compression device itself, but alternatively through an external defibrillator.

In a still further aspect of the present invention, methods for defibrillating a patient in ventricular fibrillation, comprise placing an electrode on the patient's heart, typically by percutaneously introducing an expansible electrode structure through an intercostal or other access hole. In some instances, a subxiphoid approach could be used, but it will generally be less preferred. A counter electrode is placed externally on the patient's skin, typically on the back beneath the heart. Impedance is then measured between the electrode on the heart and the counter electrode, typically by applying a small electrical potential and determining current flow to calculate the electrical impedance. The impedance measurement may be taken during a test pulse, typically using a small electrical potential as just described, or during actual treatment pulses. In some cases, it may be advantageous to monitor cardiac impedance during each treatment pulse in order to determine if changes have occurred. In the latter case, it may be desirable to then adjust the defibrillation energy parameters in response to any observed changes in impedance. The amount of defibrillation energy delivered to the heart through the electrode and counter electrode can then be determined based at least in part on the measured impedance. Typically, patients having a higher electrical impedance between the two electrodes will be initially treated at a slightly higher defibrillation energy than those having lower impedances. In particular, higher observed electrical impedances will mean that either voltage potentials and/or current delivery times will have to be increased in order to achieve the needed level of defibrillation energy.

Still further according to the present invention, methods for positioning an electrode structure over the heart are provided. Such positioning methods are particularly useful for positioning a percutaneously introduced, expansible electrode structure which has been introduced through an intercostal or other small hole in the chest wall. It will be appreciated that the precise position of the heart within the chest cavity will vary slightly from patient to patient. Thus, even though placement of the electrode through a predetermined location, such as the fourth or fifth intercostal space, will generally result in a predicable placement over the heart, the precise placement cannot be known. By providing an electrode structure having at least two isolated regions, and preferably three or more isolated regions, positioning feedback can be obtained. After initially engaging the electrode structure over the heart or pericardium, the electrical activity of the heart can be monitored through each of the electrode regions, typically by employing conventional

ECG/EKG circuitry. If fewer than all of the isolated regions show electrical activity, it is likely that the electrode structure does not lie in complete contact with the heart or pericardium. Thus, the electrode structure can be repositioned until electrical activity is observed from a maximum number of the isolated electrode regions, preferably from all of the regions. Electrical activity can be observed individually in each region, or alternatively a total activity emanating from all the regions can be monitored and maximized. After the electrode has been properly positioned, it is available for defibrillation, pacing, cardiac compression, or any other therapeutic technique as described herein.

In addition to the methods described above, the present invention comprises apparatus and systems for treating and monitoring cardiac dysfunctions. In a first aspect of the apparatus, a defibrillator comprises an enclosure, a battery power source (capable of generating high voltages) within or otherwise attached to the enclosure, one or more capacitors within the enclosure connected to the battery power supply, circuitry within the enclosure connected to the capacitors to produce a defibrillation waveform, optionally circuitry within the enclosure for monitoring ECG/EKG, optionally a visual display on the enclosure connected to the monitoring circuitry for showing at least the ECG/EKG, a control panel on the enclosure for controlling the monitoring and defibrillation circuitry, and ports on the enclosure for removably connecting ECG/EKG electrode(s), a cardiac electrode deployment device, and an external (or counter) electrode pad. The defibrillators of the present invention are intended for use with percutaneous cardiac electrodes which have quite different power requirements and limitations than do both external defibrillators and internal defibrillators. As a result of these differences, the defibrillators can be made much smaller than conventional external defibrillation equipment. In particular, the defibrillators, including all the recited components, will together weigh less than 1.5 kg, preferably less than 1 kg, and most preferably less than 0.5 kg. In addition to the small size, the defibrillator waveform circuitry will usually be limited, either by software or hardware, to produce a maximum defibrillation energy of 120 joules, preferably being lower as described above in connection with the defibrillation methods.

In the preferred embodiments, the defibrillator will further include circuitry for producing a pacing waveform. The circuitry may be connected directly to the batteries and will produce a much smaller signal than associated with defibrillation, typically being less than 150 mA, preferably being in the ranges set forth above. The

preferred defibrillators may also include circuitry for producing a timing signal to permit synchronous pacing, i.e., a pacing signal which is synchronous with the rhythm of direct cardiac compression. The circuitry may produce a pacing pattern, either visibly or audibly, which the user then follows in performing mechanical compression. Alternatively, the circuitry may trigger the pacing signal upon each mechanical compression stroke, e.g., working through a motion sensor, a force or pressure transducer, or a limit switch present in the cardiac compression device. Alternatively, some combination of the two approaches may be provided. Although described in connection with a defibrillator, it will be appreciated that the pacing circuitry may be employed in some instances by itself in systems where defibrillation is not necessary.

The defibrillation circuitry may produce any conventional defibrillation waveform. Both conventional and less common defibrillation waveforms are well-described in the patent and medical literature, and Applicants specifically incorporate the disclosures of the following U.S. patents herein by reference: U.S. Patent Nos. 5,913,877; 5,908,442; 5,899,924; 5,833,712; 5,824,017; 5,725,560; 5,634,938; 5,605,158; 5,591,209; 5,514,160; 5,447,518; 5,413,591; 5,411,525; 5,184,616; 5,083,562; and 5,014,701. For example, the percutaneous defibrillation methods and apparatus of the present invention may employ a square waveform, such as that described in U.S. Patent No. 5,205,284, assigned to Zoll, or a biphasic truncated exponential (BTE) waveform. Either the square waveform or the BTE waveform are suitable because they are biphasic and reduce the overall energy necessary to achieve defibrillation. Reduced energy generally presents less risk to the patient and allows smaller, lighter components to be employed in the apparatus of the present invention.

The defibrillators of the present invention may incorporate further circuitry which is intended to enhance their operation with the percutaneous cardiac compression, defibrillation, and pacing methods herein. For example, the defibrillator may include circuitry intended for connection to an external end-tidal carbon dioxide (CO_2) sensor, such as a sensor located in the breathing tube inserted into the patient's trachea. End-tidal CO_2 provides useful feedback on the effectiveness of the cardiac compression, pacing, and/or defibrillation since it is a reasonably good indicator of induced blood circulation. The defibrillator may include additional circuitry to perform a number of alternative functions. For example, circuitry may be provided for receiving input and feedback from the connected cardiac electrode and/or compression device. Such feedback signals include, for example, compression force measured by a transducer on a cardiac

compression device, compression repetition rate, electrical impedance, ultrasound sensing and display, video display for an optional endoscopic video system which may be built into the cardiac compression device, and the like. The feedback may be displayed to the user by means of the visual display, or alternatively using a speech synthesis capability within the defibrillator. Alternatively, visual or audible alarms may be provided based on certain defined limits. For example, excessive compression force may result in an alarm condition to alert the user to use less force. For compression/electrode surfaces having an area in the range from 20 cm^2 to 100 cm^2, the minimum effective compression force will be in the range from 1 lb, to 2 lb, while the maximum safe compression force will be 15 lb, usually being in the range from 3 lb, to 12 lb. System alarms can also be provided to alert the user when an inadequate relief of the compression force occurs during cycling. An inadequate relief of the compression force can result in inadequate filling of the heart between successive decompression and compression steps. Other possible alarm conditions include improper electrode impedances (indicated a broken lead or bad connection), inadequate compression rates, unacceptable end tidal CO_2 levels, and the like.

The defibrillators described above may be incorporated into defibrillator systems which further include at least an ECG/EKG electrode which removably connects to an electrode port on the defibrillator and a cardiac deployment device which removably connects to the cardiac electrode port on the defibrillator. Usually, the defibrillator systems will further include an external counter electrode pad which removably connects to an external electrode port on the defibrillator. The systems may be packaged together in conventional medical system packaging, such as boxes, trays, pouches, or the like. In a preferred embodiment, the external electrode pad or counter electrode will be oversized compared to conventional defibrillation paddles and pads. Usually, the oversized external electrode will have an area of at least 50 cm^2, preferably at least 80 cm^2, and more preferably at least 120 cm^2, or larger. The large electrode area may be placed beneath the heart on the patient's back and helps assure that defibrillation energy from the cardiac electrode in contact with the heart will disperse widely to effectively treat all regions of the heart. It will generally be undesirable, however, to utilize an external electrode having an area significantly larger than 150 cm^2 since too great a dispersion of the defibrillation energy will result in ineffective defibrillation and/or require the use of much higher defibrillation energies.

The present invention still further provides a hand-held defibrillation device comprising a shaft, an electrode structure deployable from the shaft to engage a surface of the heart, and a handle attached to the shaft. The handle will hold or otherwise carry the components necessary for performing defibrillation, including at least a high voltage battery power source, one or more capacitors connected to the power source, and circuitry connecting the capacitors to the electrode structure to produce a defibrillation waveform. Usually, the handle or other component of the defibrillation device will provide for connection via a cable to an external electrode pad, generally as described above in connection with the other defibrillator systems of the present invention. Preferably, the electrode structure is deployable from a low profile configuration that can be introduced through a percutaneous intercostal access hole to a deployed configuration wherein an electrode surface on the electrode structure engages an area on the heart of at least 10 cm^2, preferably from 30 cm^2 to 60 cm^2, and more preferably from 40 cm^2 to 50 cm^2. Optionally, the hand-held defibrillation device may further comprise circuitry in the handle for producing a pacing signal, wherein the user may compress the heart using the handle in response to the pacing signal to synchronize pacing and compression. The relatively low energy requirements of the percutaneous pacing protocols of the present invention permit the system components to be relatively small. Thus, the total handle volume will preferably be kept below 200 cm^3, or preferably below 100 cm^3. Additionally, the total weight of the hand-held defibrillation device will be preferably below 0.5 kg. In the most preferred embodiments, the hand-held defibrillation device will be capable of automatic performance, i.e., the device will sense and monitor the patient's ECG/EKG and deliver defibrillation energy according to predetermined patterns. After an initial defibrillation shock, the circuitry within the hand-held defibrillation device will determine whether the patient is still in ventricular fibrillation, if so, a second shock will be delivered, and subsequent shocks delivered up until a maximum energy delivery as described above.

In addition to the above, the present invention provides electronic instruments including an enclosure, an electronic display, typically a visual display such as an LCD display, attached to the disclosure, and means for adjusting the orientation of the text and/or image presented in the electronic display. The device will be capable of being repositioned, typically in a vertical or horizontal position, and the adjusting means will be responsive to such repositioning of the device so that the text or image in the electronic display will always appear in an upright fashion to the user. The orientation

adjusting means may comprise a gravity-responsive switch, typically a two-position switch which changes the image orientation between horizontal and vertical depending on the switch position. Preferably, the instrument will be a defibrillator including some or all of the specific components described above. The defibrillator or other instrument may further comprise suspension hooks clamps, or other fasteners located on different positions of the enclosure to permit hanging in vertical, horizontal, and/or other orientations.

The present invention still further provides cardiac electrode deployment devices comprising a handle and a deployable electrode structure attached to the handle. The electrode structure will have an active surface which can be shifted between a low profile configuration or it can be intercostally introduced to a region of the heart or pericardium and an open configuration where the active surface can be engaged against the heart. In particular, the cardiac electrode deployment devices will comprise a switch, preferably on the handle, to turn on and off current flow through the handle to the electrode structure. While prior percutaneous defibrillation devices relied on switches on the separate defibrillator power supply, the inclusion of a switch on the deployable electrode structure itself is advantageous since it eliminates the need for the user to reach for the separate defibrillator box. Even though the energy levels delivered in percutaneous defibrillation are far below those delivered in external defibrillation, it is still desirable that the user be able to employ a single hand when delivering the energy, thus avoiding accidental shock and injury. Usually, the cardiac electrode deployment devices will be configured to be introduced through a percutaneous intercostal penetration while the electrode structure is in the low profile configuration. Such cardiac electrode deployment devices may further comprise an energy limitation element in addition to the manual switch. The energy limitation element will prevent the delivery of energy above a preselected maximum to be used in the percutaneous defibrillation methods. The maximum will usually be 120 joules or less, preferably being 100 joules or less, and most preferably in the range from 10 joules to 60 joules. The energy limitation element may be the system software, i.e., being in the programming to limit the maximum applied energy, and/or may be in the system hardware, i.e., comprising a fuse, circuit breaker, electronic shunt, or the like, built into the energy applying circuits. Preferably, the limitation will be present in both the software and hardware.

In addition to the methods and systems described above, the present invention comprises a variety of kits employing percutaneous cardiac electrodes and/or

compression structures, together with instructions for use setting forth any of the methods described above. The kits may further comprise other system components, such as external (counter) electrode pads, connecting cables, extra batteries, ECG/EKG electrodes, and the like. Additionally, the kits may comprise packaging, such as boxes, trays, tubes, pouches, and the like. Usually, at least the percutaneous cardiac compression and/or compression devices will be maintained sterilely within the packaging. The instructions for use may be printed on a separate sheet or booklet, or may be included in whole or in part on the packaging itself.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is schematic illustration of a cardiac electrode deployment device constructed in accordance with the principles of the present invention.

Figs. 2A-2H illustrate alternative electrode structure configurations for the device of Fig. 1.

Fig. 2AA illustrates an exemplary electrically conductive fabric comprising conductive and non-conductive threads.

Fig. 3 is a perspective view of an exemplary cardiac electrode deployment device of the present invention.

Fig. 4 is a detailed view of the distal end of the device of Fig. 3 shown with the electrode deployment structure in its open or expanded configuration.

Figs. 5 and 6 illustrate an alternative, hinged-strut structure in a retracted and deployed configuration, respectively.

Figs. 7A-7C illustrate use of the device of Figs. 3 and 4 in the simultaneous cardiac compression and cardiac defibrillation methods of the present invention.

Fig. 7D illustrates use of a device having an integral counter electrode configured to engage an interior surface of the patient's rib cage.

Fig. 7BB illustrates manual dissection of an intercostal opening prior to introducing a device according to the method of the present invention.

Fig. 8 illustrates a preferred defibrillator system comprising a defibrillator, a cardiac electrode deployment or compression device, an ECG electrode(s) pad, and an external counter electrode, constructed in accordance with the principles of the present invention.

Fig. 9 is a block circuit diagram showing the components of the defibrillator of Fig. 8.

Fig. 10 illustrates a hand-held defibrillation device constructed in accordance with the principles of the present invention.

Figs. 11A-11C are a charts illustrating exemplary treatment protocols according to the methods of the present invention.

Figs. 12A and 12B illustrate exemplary defibrillation waveforms which may be used in the methods of the present invention.

Fig. 13 illustrates a system according to the present invention employing *in situ* optical imaging.

Fig. 14 illustrates a system according to the present invention incorporating *in situ* ultrasound imaging.

Fig. 15 illustrates a system according to the present invention employing a vacuum system for enhancing adherence of an electrode structure/compression element to a hard or pericardial surface.

Fig. 16 illustrates an exemplary kit constructed in accordance with the principles of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

According to the present invention, methods, systems, and kits are provided for treating and optionally monitoring patients suffering from cardiac failure. The cardiac failure may be manifested in ventricular fibrillation, ventricular tachycardia, asystole, pulseless electromechanical activity (PEA), and the treatments may comprise defibrillation or pacing, usually in combination with direct percutaneous cardiac compression. In direct cardiac compression, a cardiac electrode and/or compression structure is contacted against the heart, and such direct contact permits effective monitoring and treatment of the cardiac failure as described in detail below.

The present invention will find its greatest use in minimally invasive procedures where the electrode and/or compression structure is introduced to a region over the heart via a percutaneous access route. A preferred percutaneous access route is intercostal, typically through the fourth or fifth intercostal space and directly over the heart. In such instances, the electrode/compression structure may be introduced in a generally anterior-posterior direction so that direct contact and/or compression of the heart could be achieved by engaging the structure against the heart. More specifically,

the electrode/compression structure will usually engage the pericardium covering the heart. For simplicity of explanation, however, the following description will refer to "engaging the heart." In come cases it might be possible to engage the epicardium directly, but such an approach will be less preferred. Alternatively, in some cases the electrode/compression structure could be introduced via a subxiphoid approach, i.e., from a point below the sternum to a region above the heart.

When the anterior-posterior approach is employed, the handle of the device will preferably be introduced through a left intercostal space in the patient's left rib cage (over the heart), with the handle of the device inclined in the mid-sagittal plane, typically at an angle in the range from 0° to 45°, preferably from 10° to 30°, toward the patient's left side, so that the device compresses the heart toward the patient's spine. The handle may have little or no inclination in the cranial-caudal plane, although some inclination may be required depending on the device entry point in the patient anatomy. If the device is deployed through a right intercostal space, similar angles but reverse orientations would be used.

In most cases, the electrode and/or compression structure will be collapsible, i.e., be shiftable between a low profile configuration where it can easily be introduced in either the intercostal or subxiphoid approach and thereafter deployed at the target region to expand the surface area of the electrode to its desired size. For example, electrodes and compression structures which are formed on or from a film, mesh, fabric, or other foldable material, may be folded or otherwise collapsed prior to introduction and deployment. In other instances, it would be possible to arrange the electrode/compression structures with discrete joints, hinge regions, or other mechanical features which allow otherwise rigid structures to be folded into a low profile configuration. In still other instances, the electrode/compression structures may be formed as or on an inflatable balloon to effect deployment. Preferably, the electrode/compression structures will be capable of being collapsed to a profile having a width in at least one direction (or diameter when circular) no greater than 20 mm, preferably no greater than 15 mm. When the device is intended for intercostal insertion, it is necessary that it be inserted between adjacent ribs. In that case, an elliptical or oval periphery will have a width along the small axis which is preferably no greater than 15 mm. The size along the long axis is less critical, typically being in the range from 15 mm to 25 mm.

The electrode structures will be used to deliver defibrillation energy directly to the heart. The defibrillation energy may take any of the forms which are

conventionally used or which have been suggested for use in external or internal defibrillation. Such waveforms are generally classified as either monophasic or biphasic. In monophasic waveforms, the current travels in only one direction, i.e., from a positive defibrillator electrode to a negative defibrillator electrode. Thus, monophasic waveforms have only one phase and no change in polarity. In biphasic waveforms, the current travels in one direction stops, and then is reversed to travel the opposite direction, biphasic waveforms thus have two phases with polarity changing with the phase change. Current defibrillation waveforms may be further classified as either truncated exponential or damped sine. The present invention will preferably use a square waveform or biphasic, truncated exponential (BTE) waveform. The BTE waveform is preferably applied with a total duration of from 10 msec to 20 msec with the positive portion having a length from about 100% to 300% of the negative portion length, where both the negative and positive portions are sharply truncated. The square waveform will sometimes be preferred since it minimizes the maximum voltage while delivering the same energy as the corresponding BTE waveform. An exemplary BTE waveform is illustrated in Fig. 12A on exemplary square waveform as illustrated in Fig. 13B. Optionally, variable energy could be used, i.e., starting at a low energy level and being raised to a higher energy level. In some cases, automatic sensing of impedance could be provided, allowing for automatic adjustment of energy output. Generally, the defibrillation energy will be applied at levels in the ranges defined above.

In addition or as an alternative to delivering defibrillation energy, the electrode structures may be utilized for pacing. Pacing requires at least one isolated electrode region on the heart to deliver electrical current pulses to induce heart contraction. Preferably, the pulses are delivered between the electrode on the heart and a counter electrode on the patient's body. The amplitude of such pacing pulses will be significantly smaller than those utilized for defibrillation, typically being in the range from 1 mA to 200 mA, usually in the range from 5 mA to 100 mA. The pacing pulse may take the form of any conventional cardiac pacing pulse waveform, e.g., square wave, sine wave, biphasic, monophasic, or other suitable waveform including truncated exponential and combination waveforms. The most common waveform will be the monophasic truncated exponential waveform which is the present standard waveform. The negative pulse of the biphasic waveform is typically shorter than the positive pulse and has a sharp end point that does not tail off to zero. In particular embodiments of the present invention, switching or sensing apparatus can be applied to coordinate the delivery of a

pacing shock with the heart compression. For example, a motion or other limit switch could be provided to deliver the pacing shock at a predetermined, repeatable point in the compression cycle which is being induced by direct cardiac massage, usually at the beginning of a compression cycle.

The electrode structures may also be utilized and configured to permit EKG/ECG monitoring. The same transmission lines which connect the isolated region(s) of the electrode structure can be connected to conventional EKG/ECG monitoring circuitry within the defibrillator or other power supply controller or control box. Usually, at least two electrode regions, and preferably three or more electrode regions on the electrode structure which contacts the heart are used for EKG/ECG monitoring. Optionally, additional EKG/ECG electrodes could be placed externally on the patient's skin. The EKG/ECG circuitry can be momentarily disconnected during therapeutic energy delivery in order to protect the circuitry from damage. Alternatively, or additionally, the EKG/ECG electrodes could be isolated or protected from the energy-delivering electrodes on the cardiac contact portion of the device.

By providing both EKG/ECG monitoring and defibrillation capabilities through the same electrode structure, information can be provided to permit the user to immediately apply defibrillation energy when appropriate. For example, the treating professional can estimate the duration of ventricular fibrillation, in order to determine how the defibrillation shock may best be administered. If it appears that the patient has been in fibrillation for greater than a predetermined period of time, such as five minutes, the professional may determine that pharmacological or other mechanical therapies are necessary. The information can also be fed back to the defibrillator and/or an associated controller to permit automatic or semi-automatic defibrillation. The EKG/ECG could also be used to automatically or manually determine the appropriate timing for pacing and/or compressing the heart. The EKG/ECG could further be used to confirm and/or adjust the position of the electrode structure on the heart based on expected waveforms, etc., as described in more detail below.

Referring now to Fig. 1, a cardiac electrode deployment device suitable for performing the methods of the present invention will be described. Cardiac electrode deployment device 12 is part of a system 10 which further includes a controller 14 (typically a defibrillator and/or pacing apparatus as discussed in more detail below) and optionally a counter electrode 16. Power supply controller 14 contains the circuitry necessary for producing the defibrillation energy, pacing energy, ECG monitoring, and

optionally cardioversion energy which can be delivered or sensed by the electrode structure 18 which is shown in its deployed configuration in broken line. Electrode structure 18 is preferably shiftable between a low profile configuration (where it is drawn rearwardly) into delivery cannula 20 and the deployed configuration shown in broken line. Most simply, the electrode structure can be formed from a plurality of resilient struts having an active electrode surface 22 at their forward ends. The struts may be collapsed inwardly by drawing shaft 24 rearwardly relative to the cannula 20, thus drawing the electrode structure 18 into the cannula. The electrically conductive surface 22 will be connected to the power supply controller 14 through a connecting cable 26. Usually, at least one connector will be provided for each electrically isolated region within the active electrode area 22, as described in more detail below.

The active electrode surface 22 may have a wide variety of configurations. Usually, the electrode surface will have a generally circular periphery, although other peripheral geometries, such as ovoid, rectangular, triangular, irregular, and the like, could also be utilized. The most simple electrode surface geometry is illustrated in Fig. 2A, where the surface 22a comprises a single, continuous electrode covering the entire circular area of the electrode structure. The electrically conductive surface may be formed in any of the ways described above.

The electrode can be formed from a wide variety of conformable, electrically conductive materials or composites. Usually, the materials will be flexible but non-distensible, most usually being formed from non-distensible fabrics. In one instance, the fabrics can be metalized, for example by vapor deposition or plating (either electro or electroless) of a conductive metal surface over a fabric matrix. More usually, however, the conductive fabrics will be formed by weaving at least part of the fabric from a metal, preferably in both directions of the weave, but in some cases only in a single direction. The metal filaments in the fabric may be disposed at each strand or fiber, optionally at every other strand or fiber, usually will be placed at least once every 100 strands or fibers, more usually at at least every tenth strand. The other strands or fibers may be formed from electrically non-conductive materials, such as polyester.

An exemplary fabric is illustrated in Fig. 2AA. The fabric 400 comprises warp 402 and woof 404 threads which are woven at right angles in a conventional pattern. Preferably, at least some of the warp threads 402 and the woof threads 404 will be electrically conductive, most preferably being a metal, such as gold, silver, stainless steel, or other electrically conductive medically acceptable metal. In the exemplary structure,

the conductive and non-conductive threads will be arranged in an alternating pattern as illustrated. Such an alternating construction provides very uniform strength and electrical conductivity characteristics. Optionally, the electrically threads will be metal wires or filaments which have been mechanically, chemically, electrochemically, optically, or otherwise etched or roughened to increase the available surface area to enhance electrical contact and conduction with the heart or pericardial surface being contacted. As a further option, the metal wires may be twisted, multifilament structures composed of a number (two or more) of smaller filaments.

A first alternative electrode configuration 22b is shown in Fig. 2B, where a pair of semi-circular electrode regions 30 and 32 are spaced-apart on the exposed surface of the electrode structure. The two isolated regions are electrically isolated from each other and connected independently through the shaft 24 by isolated electrical connectors. This way, the electrode regions 30 and 32 can be energized separately or commonly, depending on how the power supply controller 14 is arranged. The isolated electrode configuration of Fig. 2B is particularly useful for applying to the surface of the heart so that the non-electrode region 34 can be placed over the conductive bundle of the heart. In this way, the conductive bundle can be protected from direct delivery of electrical current.

A second alternative configuration comprising a pair of concentric ring electrodes is shown in Fig. 2C. The concentric ring electrodes could also be laterally spaced-apart, as shown in the electrode surface 22d shown in Fig. 2D. In particular, the plurality of opposed C-shaped electrode surfaces 40, 42, 44, and 46, may be formed on the electrode support.

An electrode surface 22e comprising four pie-shaped isolated electrode regions 50, 52, 54, and 56, is illustrated in Fig. 2E. A similar electrode surface 22f comprising eight pie-shaped isolated electrode regions 62-74 is illustrated in Fig. 2F. An additional electrode configuration 22g comprising four pie-shaped electrodes further divided into concentric rings, for a total of eight isolated electrode regions 80-94 is illustrated in Fig. 2g. Finally, a rectilinear array of electrode regions 22h is illustrated in Fig. 2H. It will be appreciated that such electrode configurations can easily be fabricated using a variety of metal deposition techniques, where an electrically conductive metal, such as titanium, stainless steel, silver, gold, and copper, can be deposited, plated, or otherwise coated and patterned onto a suitable electrode substrate.

Referring now to Figs. 3-6, an exemplary cardiac electrode deployment device constructed in accordance with the principles of the present invention comprises a

sleeve 102, a shaft 104 slidably mounted in a central lumen of the sleeve 102, and a handle 106 attached to a proximal end of the shaft. The sleeve 102 includes a positioning flange 110 near its distal end, typically spaced proximally of the tip 112 of the device by an optimum distance, generally as set forth above. A blunt cap 120 is positioned at the distal-most end of the device 100 and facilitates entry of the device into the chest cavity following tissue dissection, as described in more detail hereinafter.

A flared bell structure 130, as best seen in Figs. 4 and 6, is attached to the distal end of shaft 104 and assumes a trumpeted configuration when fully deployed, as shown in both of those figures. The flared bell structure 130 comprises a plurality of outwardly curving struts 132 (the illustrated embodiment has a total of eight struts, but this number could vary). The struts are preferably formed from a resilient metal, usually formed from a superelastic alloy, such as nitinol. The use of such resilient materials will not always provide the degree of rigidity desired for the forward surface 136 (Fig. 6) of the flared bell structure. To enhance the rigidity and pushability of the structure, reenforcing beams 138 may be provided. It has been found that the combination of the curved struts with reinforcing beam supports provides a useful combination of stiffness over the proximal portion of the structure and greater flexibility at the tip portions.

The blunt cap 120 is mounted on a rod 140 (Fig. 6) having an electrical connector 142 at its proximal end. When the sleeve is advanced distally over the flared bell structure 130, the forward tip of the sleeve will engage the rear of the end cap 120, as best seen in Fig. 18. When the sleeve is retracted and the flared bell structure deployed, as best seen in Fig. 19, end cap 120 will be free to move axially. In use, the end cap will typically be withdrawn proximally into the interior of the structure 130.

The distal tips of the struts 130 are preferably connected by a fabric electrode structure 150 having an edge which is folded over and stitched to hold the cover in place. The fabric cover may be a light mesh, composed of polyester or the like, and will help distribute forces quite evenly over the region of the pericardium which is contacted by the flared bell structure.

The fabric electrode structure 150 may have any of the configurations set forth above in Figs. 2A-2H. The isolated region(s) on the electrode surface are electrically connected through a plurality of conductors (not shown) which terminate in the electrical connector 142. The connector 142 will typically include an array of plug prongs or receptacles which permit inner connection of the connector with a cable,

e.g., cable 26 as shown in Fig. 1. The cable in turn, connects the device to a suitable power supply controller.

Referring now to Figs. 7A-7C, the electrode deployment device 100 can be introduced into a region over the heart and used for direct cardiac massage. Initially, a small incision I is made over the heart, preferably on the patient's left side between the forth and fifth ribs (R_4 and R_5). Alternatively, it is possible to introduce the electrode deployment device from the right side, particularly if that approach can improve the angle for pumping the heart when cardiac compression is employed. After the incision I is made, the device 100 is pushed through the incision with the blunt cap 120 protecting the edge of the device from catching the tissue until the flange 110 engages the outer chest wall, as illustrated in Fig. 7B. Optionally, after the incision has been made, the physician or other treating personnel may manually dissect the incision which has been made, as illustrated in Fig. 7BB. Device 100 may then be pushed through the dissected incision as shown in Fig. 7B. At that point, the flared bell structure is still not deployed. The flared bell structure 130 is then deployed by advancing shaft 104 until a first marker 160 approaches the proximal end 162 of the sleeve 102. Once the structure 130 is fully deployed, the handle 106 may be manually grasped and the device shaft 104 pumped through the sleeve 102. This will cause the deployed flared bell structure 130 to engage the electrode surface against the heart. The structure can then be advanced in a posterior direction to compress the heart, generally shown in broken line in Fig. 7C. Preferably, the handle will be inclined from 20° to 45° toward the patient's left in the mid-sagittal plane while being held generally vertically in the cranial-caudal plane. In this way, the electrode structure compresses the heart toward the patient's spine to maximize compression. Defibrillation energy or pacing is then applied using a power supply 170 connected via a cable 172 to the electrode structure on the flared bell structure 130 and via a cable 174 to a counter electrode 180 which is usually disposed on the patient's back. Energy is applied according to the protocols described below. Once resuscitation has been completed, the device 100 may be withdrawn by retracting the shaft 104 relative to sleeve 102 to draw the structure 130 back into the sleeve. The structure 130 will be sufficiently retracted as soon as the second marker 162 becomes visible out of the proximal end of the sleeve. Once the structure 130 is retracted, the device may be proximally withdrawn through the incision , measures taken to correct a pneumothorax, and the incision closed in a conventional manner. The electrode deployment device 100 is intended for "monopolar" operation. That is, the electrode structure on the device 100

will be connected to one pole of an associated defibrillator, pacing device, or the like. The other pole will be connected to an external electrode engaged against the patient's skin. It will also be possible to construct an electrode deployment device intended for "bipolar" operation, as described in detail in connection with Fig. 7D below.

An exemplary defibrillator 400 for use in the systems and methods of the present invention is shown in Fig. 8. The defibrillator 400 will usually be designed to be portable for surface mounting, hook suspension, or other forms of placement at the site of use, which will typically be in a hospital or at an emergency site in the field. The defibrillator will preferably have a clam shell structure with a fold-up display 402, typically a back lit LCD display or other low energy consumption display, and a base 404. The display 402 is connected to the base by a hinge 406 which permits opening and closing of the display for use and storage, respectively. The hinge 406 also permits repositioning of the display 402 relative to the base for optimal viewing. Optionally, the hinge can be provided with detents to hold the display at a plurality of discrete angles relative to the base. The defibrillator 400 will typically be multi-functional, and include, in addition to defibrillation capability, at least pacing capability and usually EKG/ECG monitoring capability. Other optional features will be discussed in more detail below. The defibrillator 400 will be configured to permit attachment of at least a cardiac electrode deployment device, such as device 12 described in detail above. The electrode deployment device 12 will be connected via a cable 406 which is attached to the defibrillator to permit the delivery of defibrillation energy through the electrode deployment device. Usually, the connection will be made by a removable connector 408 which plugs into an appropriate receptacle 410 on the base 404 of the defibrillator 400. Similarly, a counter electrode 412 (shown in broken line) will be connected to the defibrillator 400 via a cable 414. While the attachment could be permanent, it will usually be removable using a connector 416 which plugs into a receptacle 418 on the base 404. The connector will preferably be waterproof. The defibrillator will preferably be battery-powered, with a removable battery 420 being insertable into an appropriate slot or other receptacle (not shown) in the base 404. The batteries may be rechargeable and/or replaceable. A particular advantage of the systems of the present invention is that the batteries may be made much smaller (with a corresponding lower weight) because of the reduced power requirements of percutaneous defibrillation. Usually, the defibrillator 400 will also include a port 422 on the base or elsewhere for receiving a plug-in EKG/ECG pad 424. The ECG/EKG pad may be a conventional pad of the type used with portable,

external defibrillators. The base 404 will further include conventional I/O devices, usually located on the upper surface which is protected by the pull-down display 402 when the device is closed. The I/O devices may comprise keyboards, knobs, dials, cursor arrows, or the like. The devices may have dedicated functions, or may be user definable depending on the precise programming which is employed. Finally, the defibrillator 400 may have ports for external connections to a variety of external devices, including computers, conventional EKG/ECG monitors, recording devices such as strip chart recorders, external power sources, battery charges, and the like. For the transmission of digital data, the ports may be serial, parallel, SCSI, USB, infrared, radiofrequency, or modem connections, i.e., the device would include an internal modem.

Optionally, the defibrillator 400 will also include speakers or other devices for providing audible information and alerts. In some instances, the defibrillator may include speech synthesis capability to provide verbal warnings or instructions to the user during performance of a protocol. Additionally, or alternatively, other alarm features, such as lights, buzzers, and the like, may be provided on the device. Further optionally, the defibrillator 400 may include digital and/or analog recording capability for recording the EKG/ECG waveforms, the timing and level of energy delivery, pumping parameters (such as timing, force, etc.), voice recordings made using a suitable microphone built into the defibrillator or elsewhere, video signals produced by a camera on board the treatment electrode or compression device, ultrasound signals generated by a transducer on board the electrode or compression device, etc.

While described above as a defibrillator, it will be appreciated that the systems and methods of the present invention could be used for pacing, EKG/ECG monitoring, or other electrical therapy or monitoring of the heart without defibrillation. For example, as described in more detail below, provision of the ECG/EKG capability together with pacing capability will permit both monitoring and pacing of the heart to be performed in conjunction with internal heart compression or cardiac massage. For patients in asystole, or suffering from PEA, defibrillation will not normally be an effective therapy. In asystole, internal pacing combined with direct cardiac massage may be of great benefit. By further providing control circuitry within the "power supply" 400, coordination and synchronization of the cardiac compression with the pacing signal can be substantially enhanced. In some instances, it will be possible to directly trigger the pacing signal to match the manual cardiac compression rhythm, i.e., a motion sensor, force sensor, or limit switch within the system could trigger the pacing signal at the

appropriate point during each heart compression cycle. Usually, pacing is applied during the end of the diastole or point of minimum cardiac compression. Alternatively, the pacing signal could be provided in a predetermined, usually constant pattern, with a visual or audible signal provided to the user to manually coordinate the cardiac compressions with the pacing signal, i.e., the user would pace in rhythm with the light (e.g., LCD or LED) or sound which matches the pacing rhythm.

Pacing energy may be provided through a singular electrode, such as that shown in Fig. 2A, or through an array of electrodes, such as those shown in Figs. 2B through 2H. Multiple electrodes of the array would be connected to a controller and fired in a sequence selected to mimic the contractions of a naturally beating heart. For example, the atria would be paced ahead of the ventricles by approximately 0.1 to 0.15 seconds. Device orientation would be important and this could be done by aligning an external part of the device (e.g., handle) with the direction of the head or feet or other portion of the patient's anatomy. It could also be done automatically by the device, which would select ventricular and atrial electrodes from an array of electrodes.

Referring now to Fig. 9, a functional block diagram of exemplary circuitry for the defibrillator 400 is provided. A defibrillator 400 will be controlled by a microcomputer 430 which is interfaced through the user I/O capability described previously. The microcomputer will be interfaced with suitable memory and have embedded and/or programmable instructions provided in a conventional manner. It will be appreciated that specific logical functions can be implemented either in the programming of the microcomputer or in digital or analog circuitry distributed in various discrete devices within the defibrillator. For example, the signals provided by the EKG/ECG electrodes input through receptacle 422 may be processed in whole or in part by dedicated digital or analog circuitry which is well-known and described in the patent and technical literature. Alternatively, at least part of the analysis and evaluation may be performed by and programmed into the microcomputer. In any event, the microcomputer will either receive or generate data representing the patient's EKG/ECG, and that data can be used for display and/or active control of other aspects of the system, including in particular pacing of the patient. Thus, discrete digital or analog circuitry 432 may be provided to at least partially process the EKG/ECG signal. Data transmission within the defibrillator 400 will be provided by a conventional system bus 440, which communicates with, for example, a computer interface 442, having a port 444 on the base 404 (not shown). The pacing information generated by the microcomputer 430 is also delivered to

a discrete timer 446 which controls conventional pacing output circuitry 448 which feeds directly to the pacing electrodes through the receptacle 410. Similarly, defibrillation energy levels and timing will be set by the system microcomputer 430 with the set points delivered through the bus to a suitable high voltage DC-DC converter 450. The converter receives energy directly from the battery and delivers the high-voltage energy to capacitors 452. Because of the low energy requirements of the percutaneous defibrillation, the capacitors may be significantly smaller than those utilized in conventional external defibrillation. Finally, the capacitors will feed into generally conventional (but potentially smaller) defibrillation output switches 454 which are connected to the ports 410 and 418. It should be noted that the port 410 will service both the pacing electrodes and the defibrillation electrodes. In such instances, the connector 408 which plugs into the receptacle 410 can be configured to mate with the appropriate pins or other connection elements within the port 410. In this way, the pacing energy will be delivered to pacing electrodes while defibrillation energy will be delivered to the defibrillation electrodes and the wrong form of energy cannot be accidentally delivered to the patient.

In addition to the defibrillation, pacing, and EKG/ECG capabilities, the defibrillator 400 may optionally include an input 460 for a capnograph sensor to measure carbon dioxide in patient ventilation. The capnograph sensor may be conventional and located for example, in a breathing tube used to ventilate the patient. Additionally, an input port 462 may be provided to be connected to a force sensor located in the electrode or compression surface deployment device. Alternatively, the force information could be fed back through the same cable 406 into port 410. In either case, the system will then be able to alert the user if excessive or inadequate force is being applied to the heart. In contrast to conventional CPR, direct cardiac massage will use much lower compression forces, typically below 15 lb, and preferably between 3 lb to 12 lb. Application of the much higher forces which are associated with CPR can cause significant damage to the heart.

Referring now to Fig. 10, a hand-held defibrillation device 500 comprises a handle assembly 502, a shaft 504, and a deployable electrode structure 506. Discrete and/or continuous electrode surface(s) 507 are provided on electrode structure 506. The shaft 504 and deployable electrode structure 506 may generally be as described above, but in some cases a portion of the shaft 504 may be removable via a disconnect 508. By having the distal portions of the shaft and deployable electrode structure removable and

disposable, the handle 502 and proximal portions of the shaft 504 may be reusable. Of course, the entire shaft 504 may disconnect from the handle at a point much higher up in the device 500 as well.

The hand-held defibrillation device 500 includes all power and circuitry components for the defibrillation system (and optionally pacing, EKG/ECG, and other components shown in Fig. 9) within or attached externally to the handle assembly 502. In the illustrated embodiment, an electronic module 512 is located on one side of the handle, while the battery 514 and defibrillation capacitors 516 are located on another side of the handle. A slot 518 which defines the handle grip is located in the middle of the handle. An external port or connector 520 is provided for connecting cable 522 for an external ECG pad 524. Optionally, other ports or connectors (not shown) could be provided for a capnograph sensor, an external computer, or the like.

The hand-held defibrillator 500 will preferably have the defibrillation "shock" button 530 on its upper surface to facilitate triggering of the defibrillation shock while the user is compressing the heart, typically using a single hand. Provision of a shock button on the other electrode deployment devices illustrated herein, such as device 12 (Fig. 1), device 100 (Fig. 3), etc., will also preferably include a shock button where the user can depress the button while gripping the handle and compressing or otherwise manipulating the device on the patient. It is an advantage for the user to be able to both compress the heart with the device and to initiate a defibrillation shock using a single hand, most preferably with the other hand being held away from the patient to avoid shocking the user inadvertently. Optionally, the hand-held defibrillator 500 may further include a safety interlock feature (not shown) which must be disengaged prior to actuation of the shock button 530. The safety interlock can include a second button which must be simultaneously actuated together with the "shock" button or can include a cover over the shock button which must be moved before actuation. Other conventional safety interlocks would also be useful.

A first exemplary protocol for utilizing the cardiac electrode deployment device to resuscitate a patient in cardiac arrest is shown in Fig. 11A. After the device is introduced and deployed, as generally shown in Fig. 7A-7C, the heart may be compressed. Optionally, the electrically conductive surface of the bell structure 130 can be coated with an electrically conductive gel prior to introduction. The gel helps establish electrical contact and reduces the impedance between the electrically conductive surface and the heart. It will be necessary, however, when it is desired to retain electrically

isolated regions, to make sure that the conductive gel does not short adjacent regions of the electrode structure. Optionally, the electrode structure may be pre-coated with hydrogel in order to minimize the amount of hydrogel used and to reduce the risk of shorting the isolated electrode structures. Prior to, during, or immediately following such compression, the electrode structure on the device may be used to monitor the patient EKG/ECG. If the EKG/ECG is acceptable, the device can be used to perform compression until the situation is resolved, hopefully with the patient being resuscitated. If the observed EKG/ECG is not acceptable, the electrode structure can be used to apply defibrillation energy to the heart. Usually, defibrillation energy will be applied in a single step (although the step may be divided into a series of discreet, progressively more energetic applications of energy over a very short time period, as described above). Direct contact of the electrode structure with the heart allows use of relatively low defibrillation energies as discussed above. After the single application of energy has been completed, heart function will again be assessed by EKG/ECG. If the initial defibrillation has been successful, the treatment can frequently be terminated or continued with compression alone, or compression plus pacing, until the patient is resuscitated. If the initial defibrillation has been unsuccessful, i.e., acceptable EKG/ECG has not been achieved, the patient may again be defibrillated following direct cardiac massage. Third and subsequent defibrillation steps can further be provided until restoration of an acceptable EKG/ECG is achieved. If defibrillation continues to be unsuccessful, the patient can continue to be compressed until the situation is resolved, further surgical or other interventions (e.g., cardiopulmonary bypass) are initiated, or there is no reason to continue cardiac compression.

Use of a modified device 200 for resuscitating a patient is illustrated in Fig. 7D. The device 200 comprises a sleeve 202 and flared bell structure 230, as generally described above for the device 100. The device 200 differs principally in that it includes an integral second electrode 240 which serves as a counter electrode in performing defibrillation according to the present invention. The electrode 240 is expansible from a low profile configuration to an expanded configuration so that it can engage the interior thoracic wall, e.g., an interior surface of the rib cage, when the device 200 is deployed. The electrode 240 will usually be attached to the sleeve 202 so that the electrode 240 remains generally stationary against the interior thoracic wall as the flared bell structure 230 (carrying the primary electrode structure) is reciprocated to compress the heart. Defibrillation current can be applied by any of the protocols

described herein, and the current wall will generally follow the flux lines 250 shown in Fig. 7D. Cables 270 at 274 connect the power supply 280 to the primary and counter electrodes on the device 200.

Referring now to Fig. 11B, a second exemplary protocol for performing the methods of the present invention will be described. After a cardiac compression/defibrillation/pacing device is introduced and deployed, the patient's EKG/ECG will be monitored. Usually, at least some of the electrodes on the device surface which are in contact with the heart will be used for monitoring. Optionally, or alternatively, chest mounted electrode(s) can be used for EKG/ECG monitoring. For example, a single external EKG/ECG electrode pad structure can be used, where the electrode structure includes multiple separate electrode regions which are isolated from each other and which are used to obtain multiple EKG/ECG signals without the need to use more than one separate electrode assembly. Further optionally, the nature and quality of ventricular fibrillation can be assessed using Fourier pattern analysis to determine the frequency spectrum of the waveform. Components of the waveform that can be analyzed include the voltage amplitude, frequency of fibrillation, lack of diastolic plateau, and the like.

Based on the nature of the patient's EKG/ECG, a preferred course of treatment can be selected. If the patient is determined to be in asystole, i.e., no cardiac sinus rhythm, then the patient will be treated by compression optionally with pacing. Compression and/or pacing can be continued until a normal cardiac rhythm is reestablished or it is determined that the patient cannot be resuscitated. If the patient is determined to be in fibrillation, defibrillation energy will be applied to the heart as described above in connection with earlier embodiments. Compression can be performed simultaneously and/or after the heart has been defibrillated. If the patient is determined to be in tachycardia, then the device will be used to apply pacing energy directly to the heart. Optionally, the heart can be compressed simultaneously and more preferably synchronously, with the application of pacing energy. Finally, if the patient is determined to be in PEA, a preferred course of treatment will be compression only.

Referring now to Fig. 11C, in cases where the cardiac massage device is introduced without any form of imaging, it will be desirable to have a method for confirming proper placement of the deployable electrode structure over the heart. A preferred method for confirming placement of the electrode structure is to use an electrode structure having at least two, preferably three, and optionally a greater number

of isolated electrode regions on its surface. Two or more of such isolated electrode regions will be used to separately monitor EKG/ECG from the heart. It will be appreciated that if the electrode region is not in contact with the heart, the detection of EKG/ECG will be greatly diminished or absent. Thus, by monitoring ECG from each of the isolated electrode regions, and determining whether ECG is present, it can be determined whether all of these regions are in contact with the heart. Thus, after initially placing the deployed electrode structure on the heart, the device can be moved until a maximum number of the isolated electrode regions display and EKG/ECG signal. Alternatively, collective signals from the various regions can be observed, and the device can be repositioned until the observed signal is maximized. After the expanded structure is properly placed, the structure can be used compress the heart generally as described above. This placement method, of course, will not be effective with patients in asystole since there will be no waveform to observe.

The defibrillators and other cardiac electrode deployment structures of the present invention may further comprise imaging capability which permits visualization of the thoracic cavity and heart during deployment of the electrode structure. In particular, by providing a direct imaging capability on or near the electrode structure, the practitioner can guide the electrode structure to the desired target location over the pericardium or heart by visualizing the region in real time during the deployment protocol.

A cardiac electrode deployment tool 600 having a fiberoptic or rod lens viewing scope incorporated therein is illustrated in Figs. 13 and 13A. The electrode deployment tool 600 includes a sleeve 602, a shaft 604, and a handle 606, all generally the same as those described in connection with earlier embodiments. An expansible electrode structure 608 is positioned at a distal end of the device 600 and is deployable by moving the handle 606 relative to the sleeve 602. The cardiac electrode deployment tool 600 differs from prior embodiments in that it includes an optical imaging fiber or bundle 610 which extends through the sleeve and terminates in a viewing tip or lens 612. Illumination bundles 614 are also provided in the sleeve 602, and both the imaging fiber and illumination bundles are connected to a video display 618 by a connecting cable 620. The viewing display and electronics required for operating both the illumination and imaging components of the system are well-known in the endoscopic arts. The viewing display 618 may be incorporated in a defibrillator 622 which may be connected to the electrode deployment tool 600 by a second cable 624. A defibrillator 622 may generally have the form described earlier in connection with the defibrillator 400. The viewing tip

or lens 612 will be configured within the sleeve 602 so that it can view in a forward or distal direction from the sleeve so that, when the electrode structure 608 is retracted, it can see clearly forwardly of the sleeve. Alternatively, when the electrode structure 608 is deployed, it will be able to view the electrode relative to the heart H.

Referring now to Fig. 14, an additional cardiac electrode deployment tool 700 comprising sleeve 702, as shaft 704, and a handle 706, is illustrated. The tool 700 further comprises a deployable electrode structure 708 which may be retracted and deployed in a manner analogous with previously described embodiments of the deployment tools herein. Cardiac electrode deployment tool 700 is further provided with an ultrasonic imaging capability. In particular, an ultrasonic transducer 710 is provided in a distal tip element 712, which may be a blunt actuator used to assist in introducing the device via a blunt dissection. The tip element 712 will be configured so that it leads a tool 700 as it is introduced distally into the thoracic cavity through an intercostal access route, as described previously. The ultrasonic transducer 710 may be connected via an appropriate electrical cable which passes through shaft 704 and via cable 720 to an ultrasonic image display screen 722. The ultrasonic display screen 722 is shown separate from the defibrillator, but could be incorporated therein if desired. The defibrillator may be connected to the device 700 through a cable 724 which in turn is connected to an external defibrillator (not shown).

The previously described embodiments have generally shown the defibrillation, pacing, EKG/ECG, or other electrodes being positioned on the deployable electrode structure. Usually, the deployable electrode structure is also suitable for cardiac compression. As shown in Fig. 15, however, the defibrillation or other cardiac electrodes of the present invention could be incorporated into other structure which is deployed using the access probes of the present invention. In particular, balloons or other expansible electrode support structures may be deployed together with the cardiac compression structure, where the cardiac compression structure may or may not include electrode(s) on its cardiac contact surface. For example, a device 800 may include a cardiac compression structure 802 (optionally having electrodes thereon), a first electrode balloon 804, and a second electrode balloon 806. The cardiac compression structure 802, as well as the electrode balloons 804 and 806, are deployed through a sleeve 810 and a shaft 812, generally as described above in connection with prior electrode deployment structures. The balloons 804 and 806 are inflated in any conventional manner, typically using an inflation syringe 814 which may be coupled to the balloons through the

sleeve 810. Electrodes on the balloon, as well as the optional electrode on compression structure 802 will be connected to a defibrillator 830 which may optionally include pacing, EKG/ECG, or other capabilities. By including at least two laterally spaced-apart electrodes on separate deployment structures, such as balloons 804 and 806, the electrode contact areas on the heart can be more widely spaced apart then if the electrodes are present on a single deployment structure, such as the cardiac compression structure 802. Preferably, at least a first electrode structure will contact the heart near the apex while an at least second electrode will contact the heart near the base. In this way, current flow for defibrillation can run along the axis of the heart. Other more complex patterns may also be applied, particularly for defibrillation.

In all of the above embodiments, it will in some cases be desirable to provide a vacuum capability on the cardiac contact electrode structure. In order for proper defibrillation, pacing, monitoring, or other electrical procedures to be conducted, good electrical contact between the electrode structures and the heart is necessary. While the use of electrically conductive gels will improve electrical contact, it is also desirable to enhance contact by applying or drawing a vacuum between the electrode structure and the heart. Particularly in the case of the expansible electrode structures which may optionally be used for cardiac compression, it will be desirable to maintain an adherence between the structure and the heart at all times during the compression cycle (including withdrawn diastole and filling). By applying a vacuum through the deployable electrode structure, such contact can be achieved.

Referring now to Fig. 16, a kit 300 according to the present invention comprises a cardiac electrode deployment tool, such as device 100 described in detail previously, in combination with instructions for use IFU setting forth any of the methods described above. Usually, the device and instructions for use will be combined in a suitable package P that can be in the form of any conventional medical device packaging, such as a tray, tube, box, pouch, or the like. The instructions for use will usually be provided on a separate package insert, but could also be printed directly on all or a portion of the packaging P. Additional components, such as a counter electrode, could also be provided as part of the kit.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A method for defibrillation of a patient's heart, said method comprising:

providing an electrode structure having a low profile and a deployed configuration;

percutaneously introducing the electrode structure in the low profile configuration to a region over the heart;

deploying the electrode structure after the electrode structure has been introduced;

contacting the electrode structure against the heart; and

applying defibrillation energy to the heart at a level not to exceed 120 joules.

2. A method as in claim 1, wherein applying defibrillation energy comprises delivering energy from a defibrillator which prevents the user from applying energy at a level above 120 joules.

3. A method as in claim 2, wherein the defibrillator is prevented from delivering energy outside a level in the range from 0.1 joules to 100 joules.

4. A method as in claim 1, wherein applying defibrillation energy comprises (a) applying energy at a first predetermined energy level, (b) sensing whether the heart remains in ventricular fibrillation; and repeating steps (a) and (b) at a higher predetermined energy level until ventricular fibrillation ceases or the applied energy level has reached a predetermined maximum level of 120 joules or less.

5. A method as in claim 4, wherein the predetermined maximum level is 100 joules or less.

6. A method as in claim 4, wherein the predetermined maximum level is 80 joules or less.

7. A method as in claim 4, wherein the first predetermined energy level is in the range from 0.1 joule to 30 joules.

8. A method as in claim 7, wherein successive applied energy levels increase by an amount in the range from 10 joules to 20 joules.

9. A computer program in a tangible medium for use with a defibrillation, said computer program setting forth the following steps:

(a) delivering energy at a first predetermined level to a heart in ventricular fibrillation;

(b) sensing whether the heart remains in ventricular fibrillation;

(c) if the heart remains in ventricular fibrillation, repeating step (c) at a higher energy level, wherein steps (a) to (c) may be repeated more than once but will not be repeated after the energy level has reached a predetermined maximum level of 120 joules or less.

10. A computer program as in claim 9, wherein the initial energy is delivered at a level in the range from 0.1 joule to 30 joules, and the incremental increases are in the range from 10 joules to 20 joules.

11. A method for resuscitating a patient in asystole, said method comprising:

contacting an electrode structure against the heart;

applying pacing energy to the heart in a rhythmic pattern; and

determining if heartbeat is reestablished.

12. A method as in claim 11, further comprising defibrillation energy to the heart if heartbeat is not reestablished in response to the pacing energy.

13. A method as in claim 11, further comprising rhythmically compressing the heart with the electrode structure.

14. A method as in claim 13, wherein the pacing energy is applied synchronously with the rhythmic compression of the heart.

15. A method for resuscitating a patient asystolic, said method comprising:

percutaneously introducing a compression structure against the heart;

pressing the compression structure to cause compression of the heart; and

applying pacing energy to the heart synchronously with pressing of the compression structure.

16. A method as in claim 15, wherein the pacing energy is applied to the heart through an electrode structure attached to the compression structure.

17. A method as in claim 15, further comprising forming a percutaneous intercostal access hole through the patient's chest wall over the heart, wherein the compression structure is introduced through the access hole.

18. A method for resuscitating a patient in cardiac failure, said method comprising:

providing a percutaneous cardiac compression device;

determining the nature of the cardiac failure from among at least asystole, fibrillation, and pulseless electromechanical activity;

percutaneously introducing the compression device;

engaging the compression device against the heart;

compressing the heart with the compression device; and in addition;

(i) if the patient is determined to be in asystole, applying a pacing energy to the heart;

(ii) if the patient is in fibrillation, applying defibrillation energy to the heart; and

(iii) if the patient is in PEA, applying no defibrillation energy or pacing energy to the heart.

19. A method as in claim 18, further comprising determining if the cardiac failure results from ventricular tachycardia, wherein the patient will be treated in addition by applying pacing energy to the heart.

20. A method for defibrillating a patient, said method comprising:

placing an electrode on the patient's heart;

placing a counter electrode on the patient's skin;

measuring impedance between the electrode and counter electrode; and

controlling defibrillation energy delivered to the heart through the electrode and counter electrode based at least in part on the measured impedance.

21. A method as in claim 20, wherein the counter electrode is placed .on the patient's back beneath the heart or on the right shoulder.

22. A method for positioning an electrode structure over the heart, said method comprising:

providing an electrode structure having at least two isolated regions;

engaging the electrode structure over the heart;

monitoring electrical activity from each of the electrode regions; and

repositioning the electrode structure until electrical activity is observed from a maximum number of regions.

23. A method as in claim 22, wherein engaging comprises percutaneously introducing the electrode structure through an intercostal access hole.

24. A defibrillator for use with a percutaneous cardiac electrode and external electrode pad, said defibrillator comprising:

an enclosure;

a battery power source within or attached to the enclosure;

one or more capacitors within or connected to the enclosure connected to the battery power supply;

circuitry within the enclosure connected to the capacitors to produce a defibrillation waveform;

a control panel on the enclosure for controlling the circuitry; and

ports on the enclosure for connecting a cardiac electrode deployment device;

wherein all the defibrillator components together weigh less than 1.5 kg.

25. A defibrillator as in claim 24, wherein the defibrillator components together weigh less than 1 kg.

26. A defibrillator as in claim 24, further comprising circuitry within the enclosure for monitoring ECG and a visual display on the enclosure for showing the ECG.

27. A defibrillator as in claim 24, wherein the defibrillator components together weigh less than 0.5 kg.

28. A defibrillator as in claim 24, wherein the defibrillation waveform circuitry produces a waveform having a maximum energy of 120 joules.

29. A defibrillator as in claim 24, further comprising circuitry connected to the batteries for producing a pacing waveform.

30. A defibrillator as in claim 24, further comprising circuitry for producing a pacing signal.

31. A defibrillator as in claim 30, further comprising circuitry for producing a pacing signal which permits a user to perform direct cardiac compression synchronously with the pacing signal.

32. A defibrillator as in claim 30, further comprising circuitry for triggering the pacing signal in response to motion of a cardiac compression device connected to the defibrillator.

33. A defibrillator as in claim 24, wherein the defibrillation waveform circuitry produces a square wave or BTE waveform.

34. A defibrillator as in claim 24, further comprising circuitry within the enclosure for monitoring end-tidal CO_2 in a patient's respiration and a port on the enclosure for connecting a CO_2 sensor.

35. A defibrillator as in claim 24, further comprising circuitry which receives feedback signals from the cardiac electrode deployment device and which produces user information in response to the feedback signals.

36. A defibrillator as in claim 35, where the feedback signals are selected from the group consisting of compression force of the electrode structure against the heart, compression rate, and impedance.

37. A defibrillator as in claim 24, wherein the user information is presented on the visual display, as a visual alarm, as an audible alarm, or as speech.

38. A defibrillator system comprising:

a defibrillator as in claim 24,

an ECG electrode which removably connects to an ECG port on the defibrillator;

a cardiac electrode deployment device which removably connects to a cardiac electrode port on the defibrillator, and an external electrode pad which removably connects to an external electrode port on the defibrillator.

39. A defibrillator system as in claim 38, wherein the external electrode pad has an area of at least 50 cm^2.

40. A hand-held defibrillation device comprising:

a shaft;

an electrode structure attached to the shaft to engage a surface of the heart; and

a handle attached to the shaft, wherein the handle carries:

(a) a battery power source;

(b) one or more capacitors connected to the battery power source; and

(c) circuitry connecting the capacitors to the electrode structure to produce a defibrillation waveform.

41. A hand-held defibrillation device as in claim 40, wherein the electrode structure is deployable from a low profile configuration that can be introduced through a percutaneously intercostal access hole to a deployed configuration to engage the heart over an area of at least 10 cm^2.

42. A hand-held defibrillation device as in claim 40, further comprising circuitry in the handle connected to the battery power source for producing a pacing signal, wherein the user may compress the heart using the handle in response to the pacing signal to synchronize pacing and compression.

43. A hand-held defibrillation device as in claim 40, wherein the volume of the handle is below 200 cm^3.

44. A hand-held defibrillation device as in claim 40, wherein the weight of the handle is below 0.5 kg.

45. A hand-held defibrillation device as in claim 40, wherein the defibrillation circuitry monitors ECG and automatically determines the energy and timing.

46. A defibrillation system comprising:
a hand-held defibrillation device as in claim 40; and
an external pad connectably to the defibrillation circuitry.

47. An electronic instrument comprising:
an enclosure;
an electronic display attached to the enclosure, said display being capable of presenting text and/or images; and
means for adjusting the orientation of the text and/or image presented in response to repositioning of the enclosure.

48. An electronic instrument as in claim 47, wherein the adjusting means comprises a gravity-responsive two-position switch which changes the image orientation between horizontal and vertical.

49. An electronic instrument as in claim 47, wherein the instrument comprises a defibrillator.

50. An electronic instrument as in claim 47, further comprising suspension hooks on the enclosure.

51. A cardiac electrode deployment device comprising:
a handle;
an electrode structure attached to the handle and having an active surface which can be shifted between a low profile configuration where it can be intercostally introduced to a region over the heart to an open configuration where the active surface can be engaged against the heart; and
a switch on the support to turn on and off current flow through the handle to the electrode structure.

52. A cardiac electrode deployment device as in claim 51, further comprising a shaft connecting the electrode structure to the handle.

53. A cardiac electrode deployment device as in claim 52, wherein the shaft is configured to pass through a percutaneous intercostal penetration when the electrode structure is in its low profile configuration.

54. A cardiac electrode deployment device as in claim 51, further comprising an energy limitation element which prevents the delivery of energy above a preselected maximum to the active surface of the electrode structure.

55. A cardiac electrode deployment device as in claim 54, wherein the preselected maximum is 120 joules or less.

56. A cardiac electrode deployment device as in claim 54, wherein the preselected maximum is 100 joules or less.

57. A cardiac electrode deployment device as in claim 54, wherein the preselected maximum is in the range from 0.1 joules to 100 joules.

58. A kit comprising:
a percutaneous cardiac electrode structure; and
instructions for use setting forth a method according to claim 1.

59. A kit comprising:
a percutaneous cardiac electrode structure; and
instructions for use according to claim 11.

60. A kit comprising:
a cardiac compression structure; and
instructions for use according to claim 15.

61. A kit comprising:
a cardiac compression device; and
instructions for use according to claim 18.

62. A kit comprising:

a cardiac electrode;

a counter electrode; and

instructions for use setting forth a method according to claim 20.

63. A kit comprising:

a cardiac electrode structure having at least two isolated regions; and

instructions for use according to claim 22.

64. A method for pacing a patient's heart, said method comprising:

contracting the heart with an array of electrodes; and

energizing individual electrodes within the array in an order selected to induce heart muscle contraction in a sequence which mimics a natural heart compression cycle.

65. A method as in claim 64, wherein the order is selected to contract the atria ahead of the ventricles.

66. A method as in claim 65, wherein the atria is contracted from 0.1 seconds to 0.15 seconds ahead of the ventricles.

67. A method as in claim 64, wherein contracting comprises orienting the electrode array in a preselected orientation prior to or after contracting the heart.

68. A method as in claim 67, wherein orienting comprises visually aligning a marker on or associated with the array relative to the anatomy of the patient.

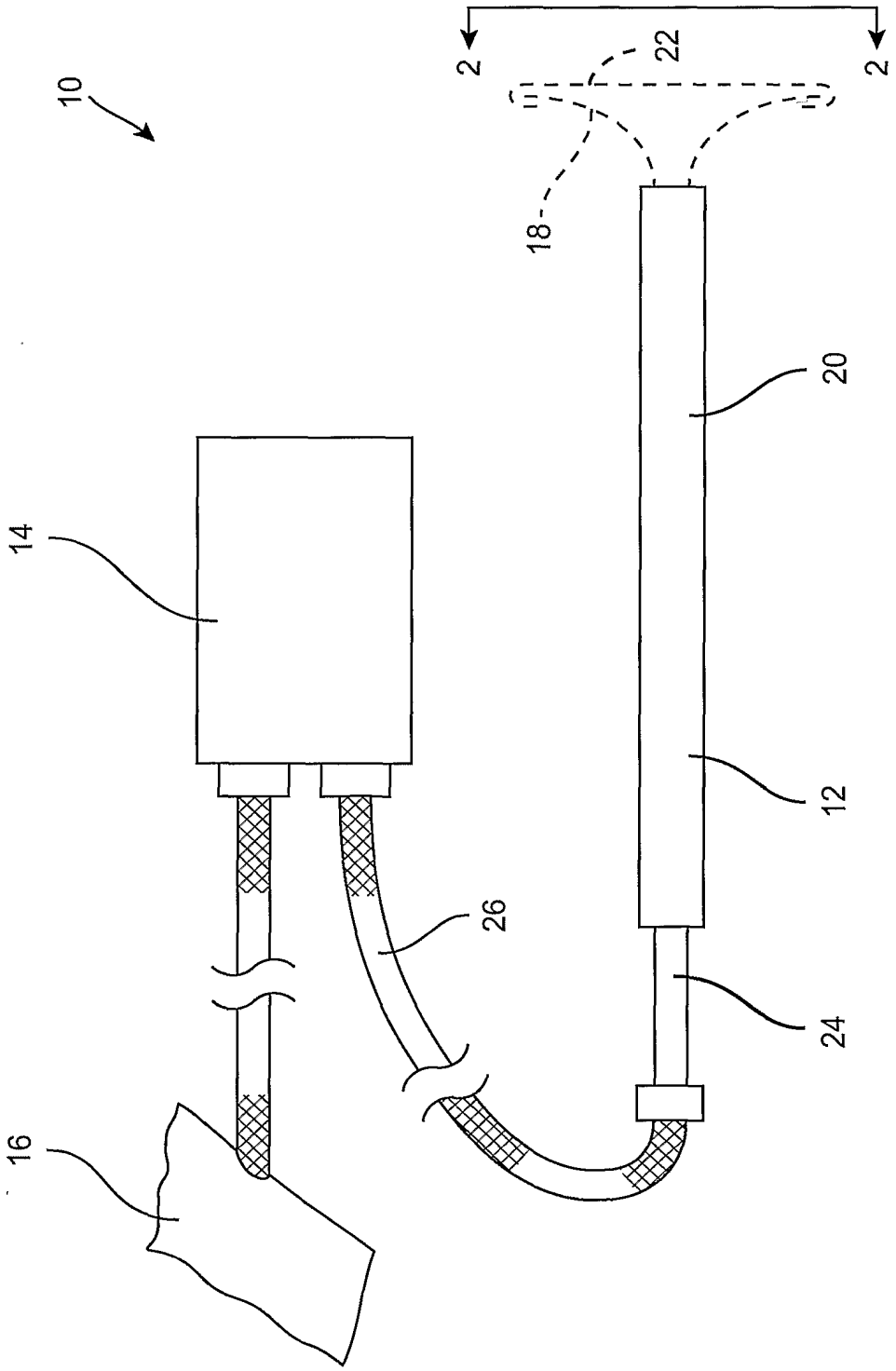


FIG. 1

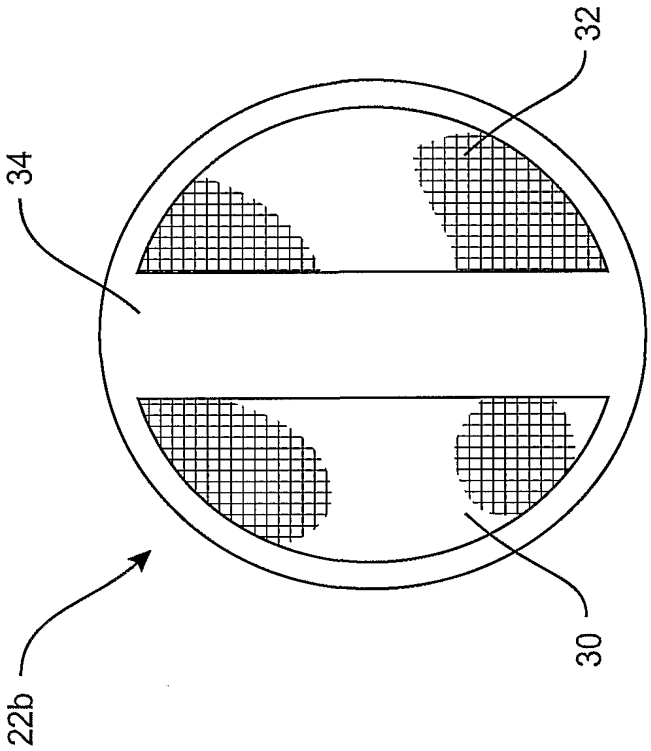


FIG. 2B

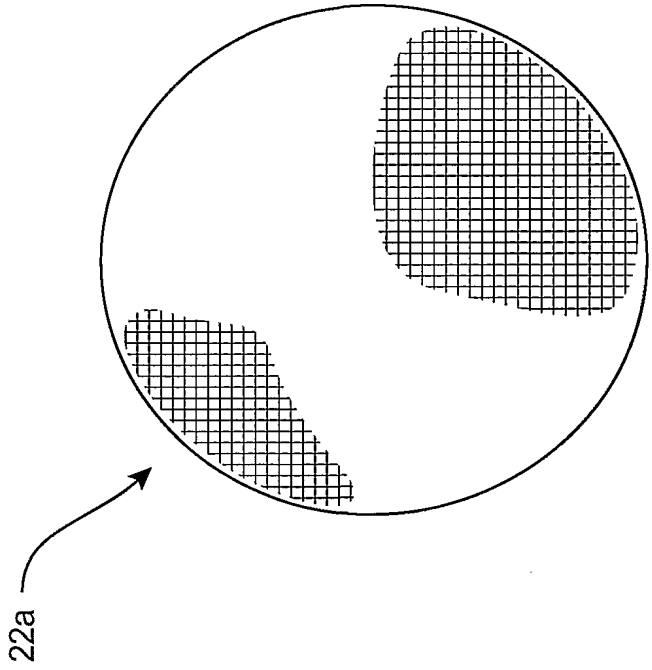


FIG. 2A

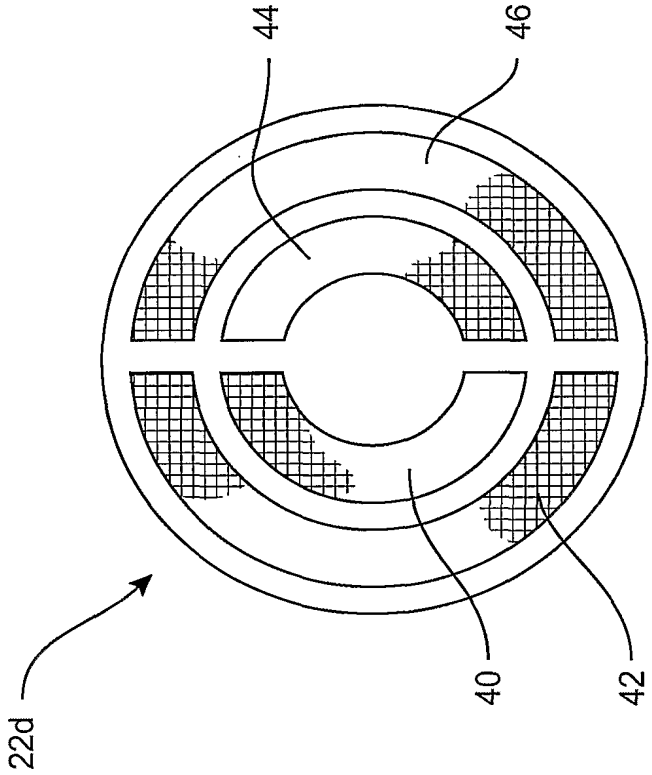


FIG. 2D

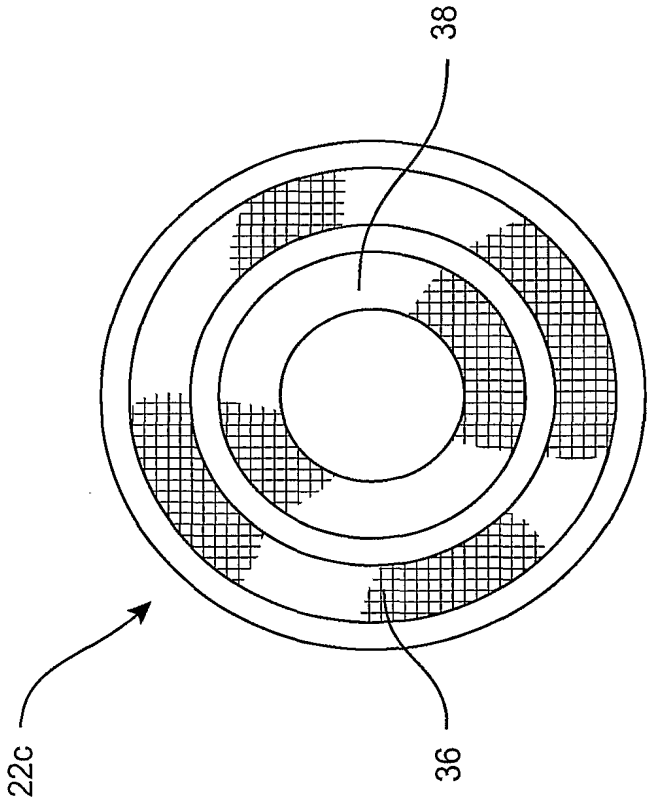


FIG. 2C

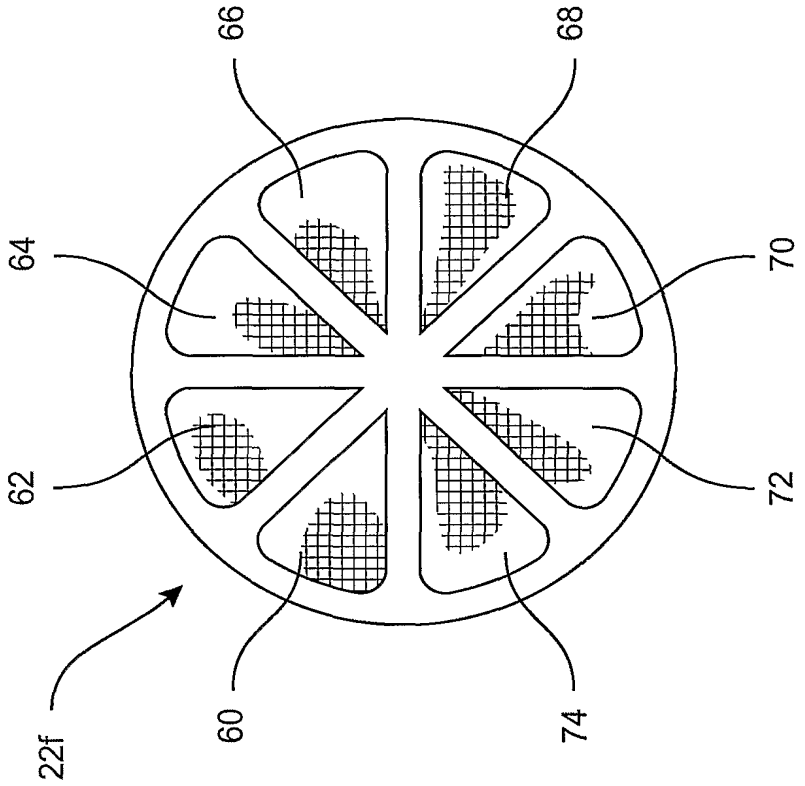


FIG. 2F

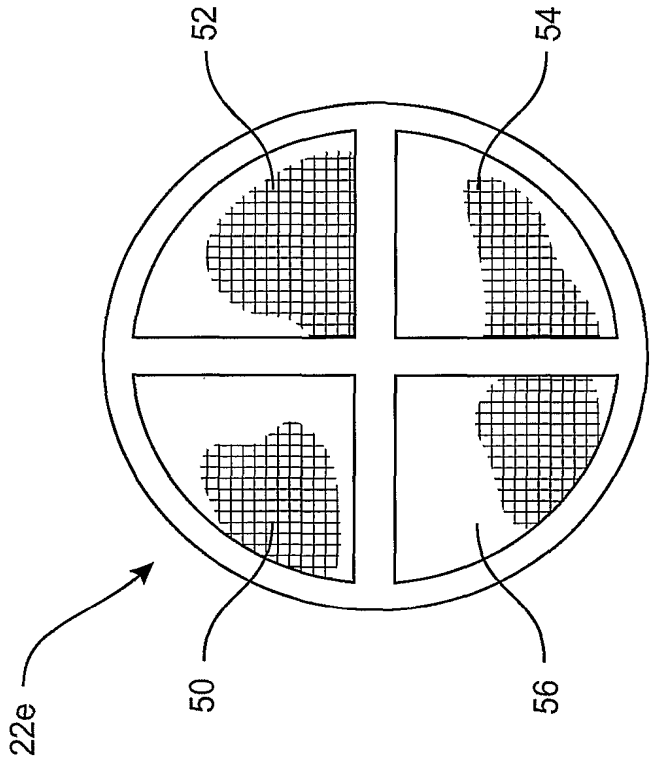


FIG. 2E

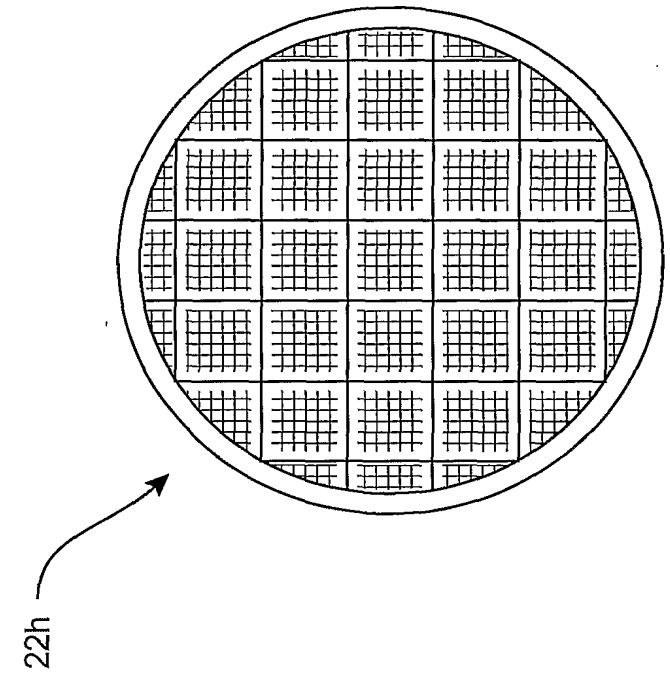


FIG. 2H

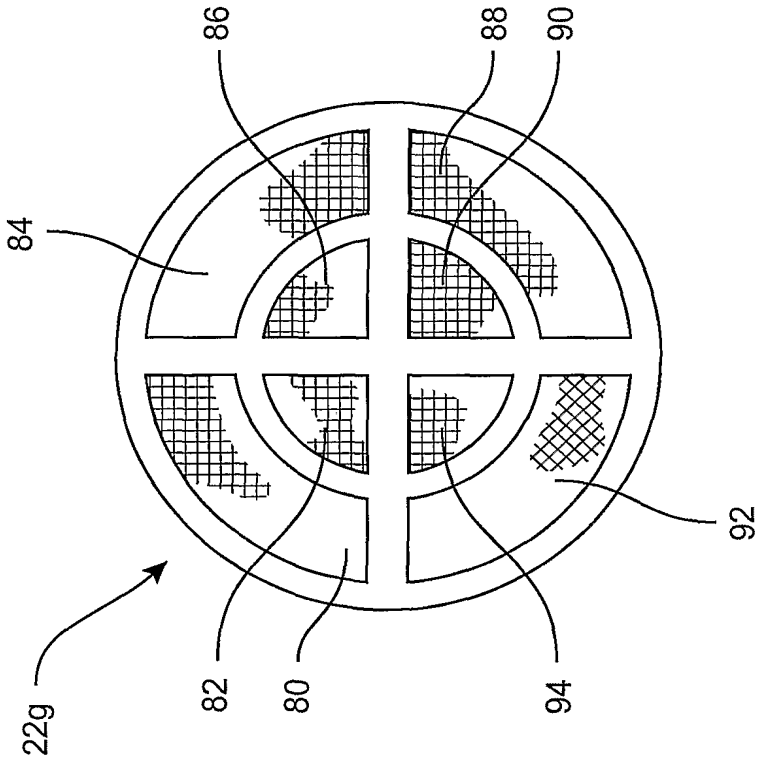


FIG. 2G

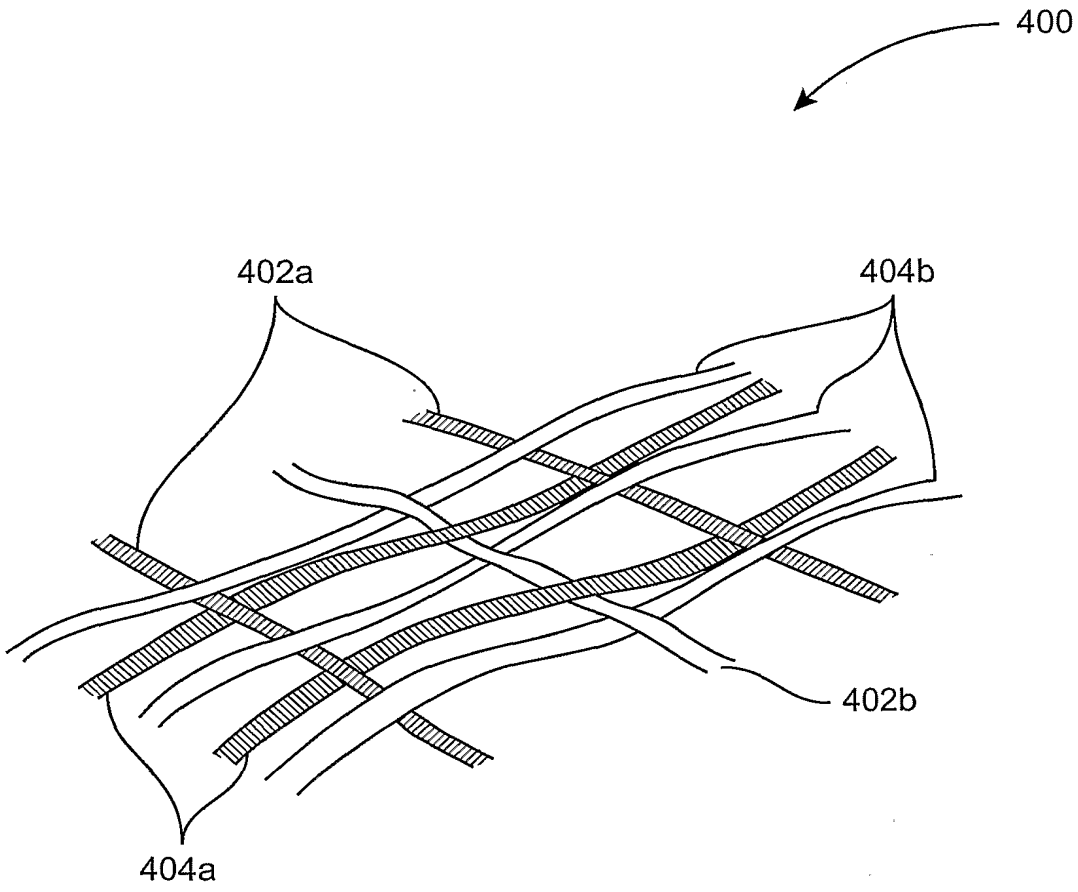


FIG. 2AA

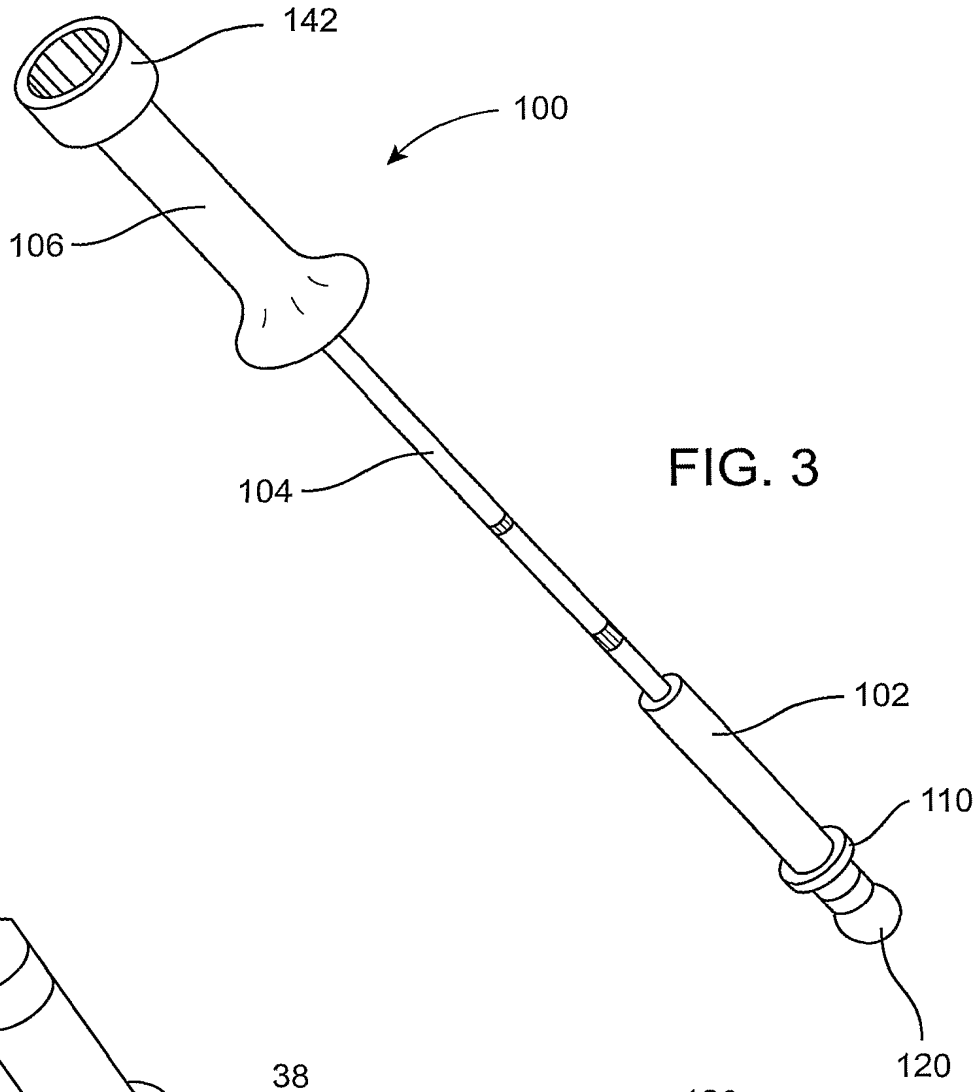


FIG. 3

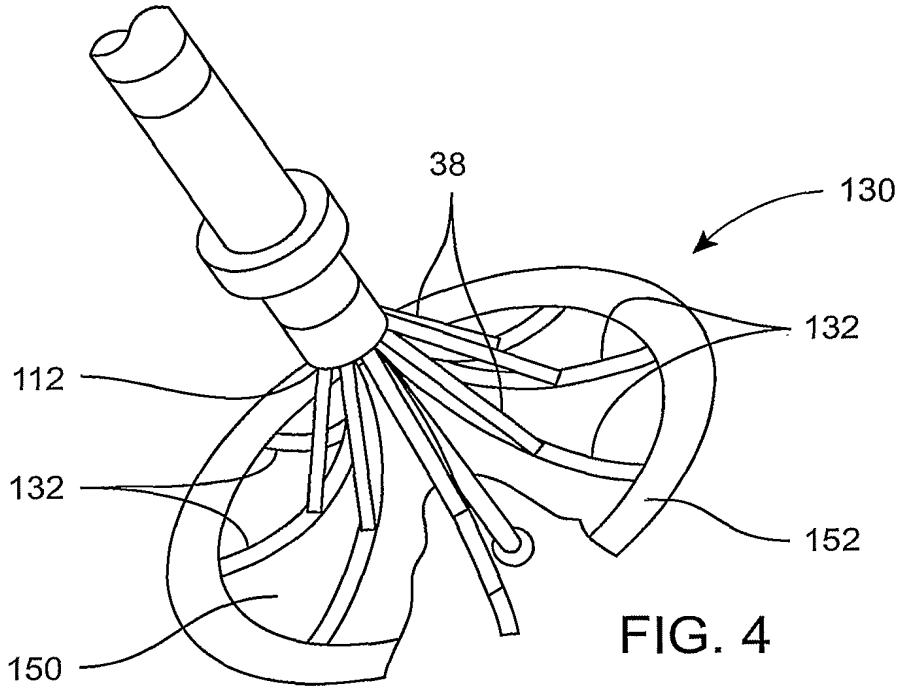


FIG. 4

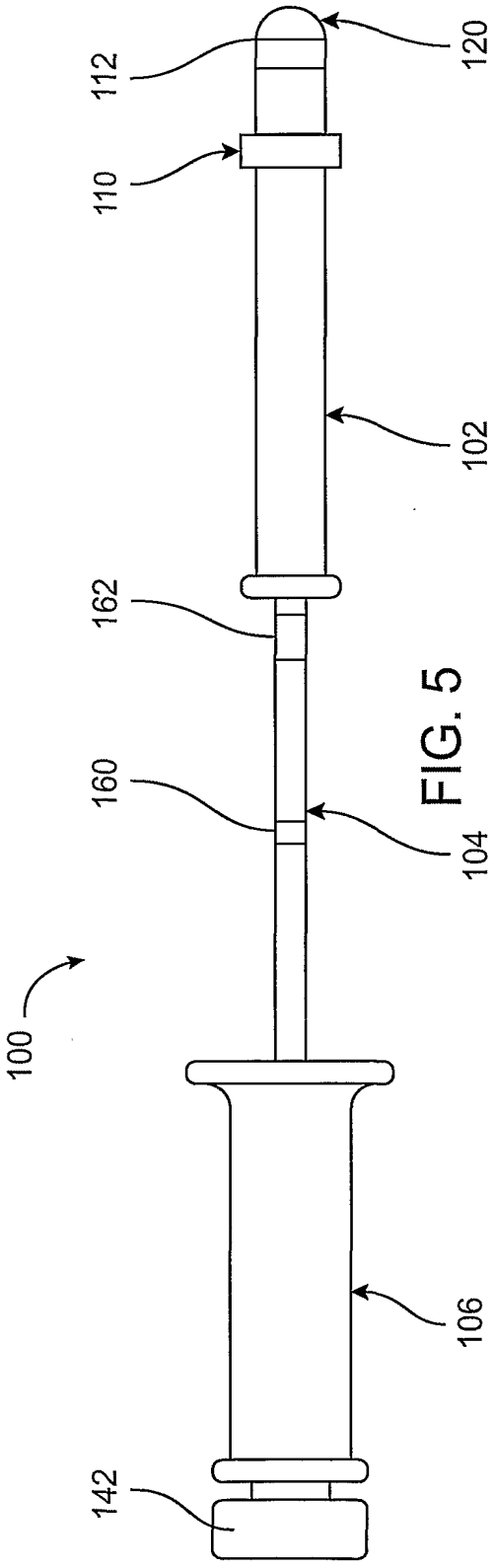

100
112
120
110
102
162
160
104
106
142

FIG. 5

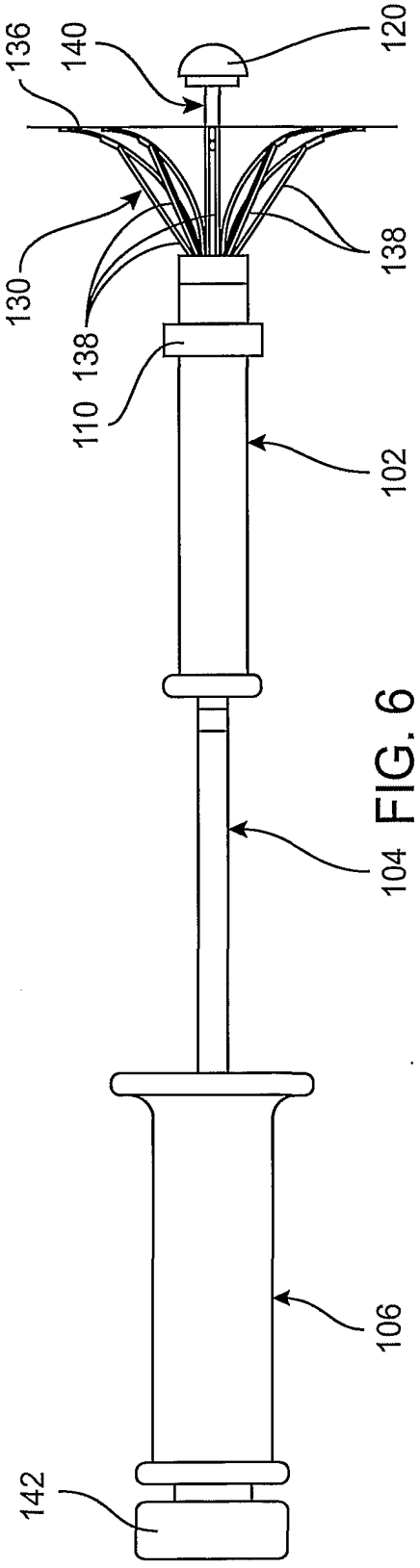

136
140
120
130
138
110
138
102
104
106
142

FIG. 6

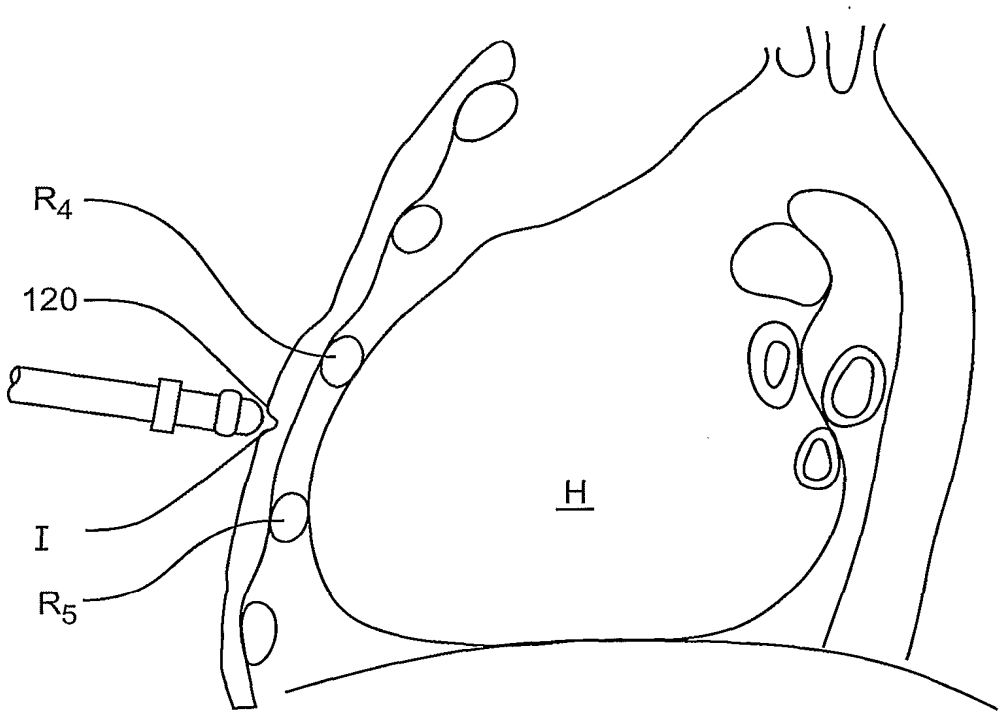


FIG. 7A

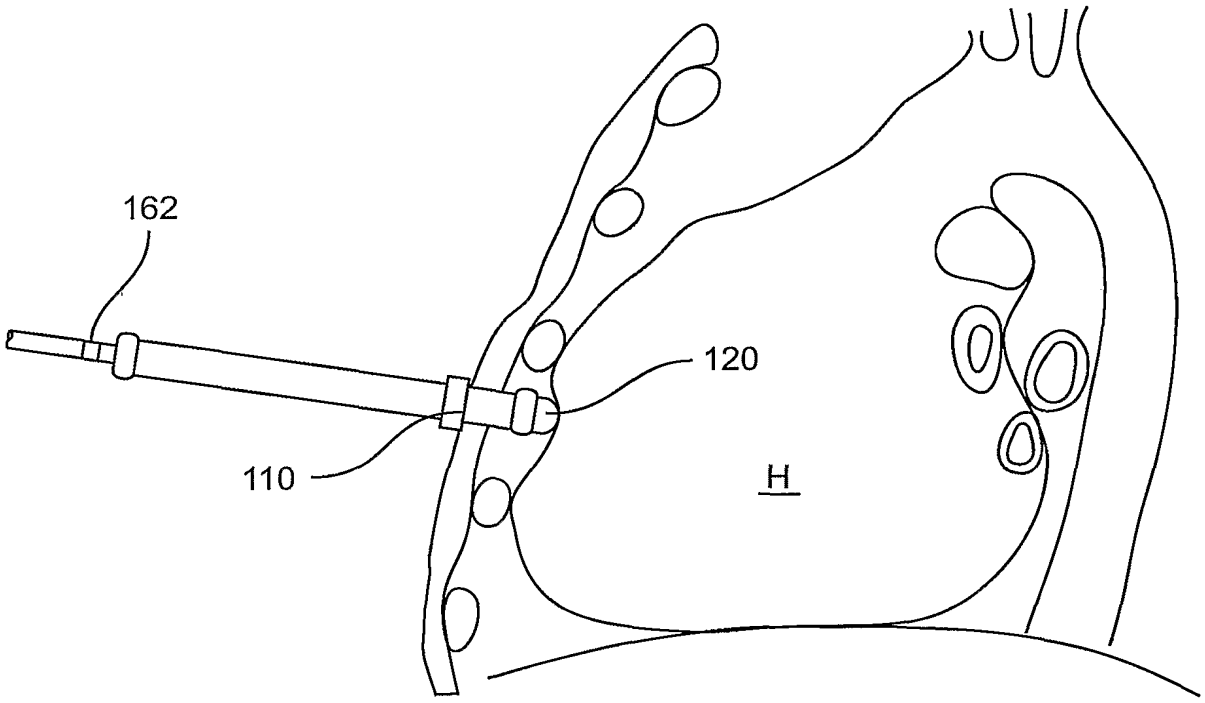


FIG. 7B

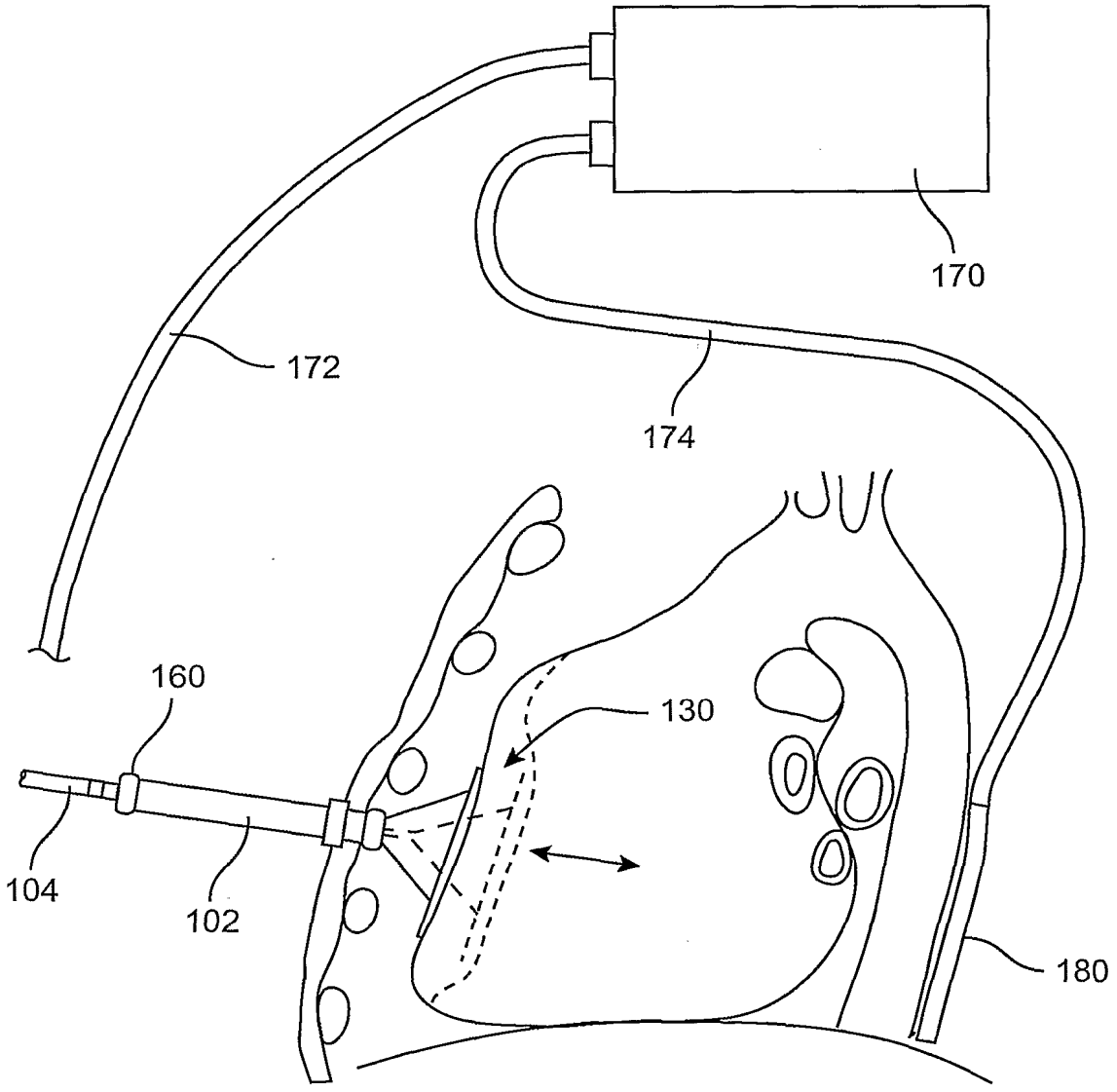


FIG. 7C

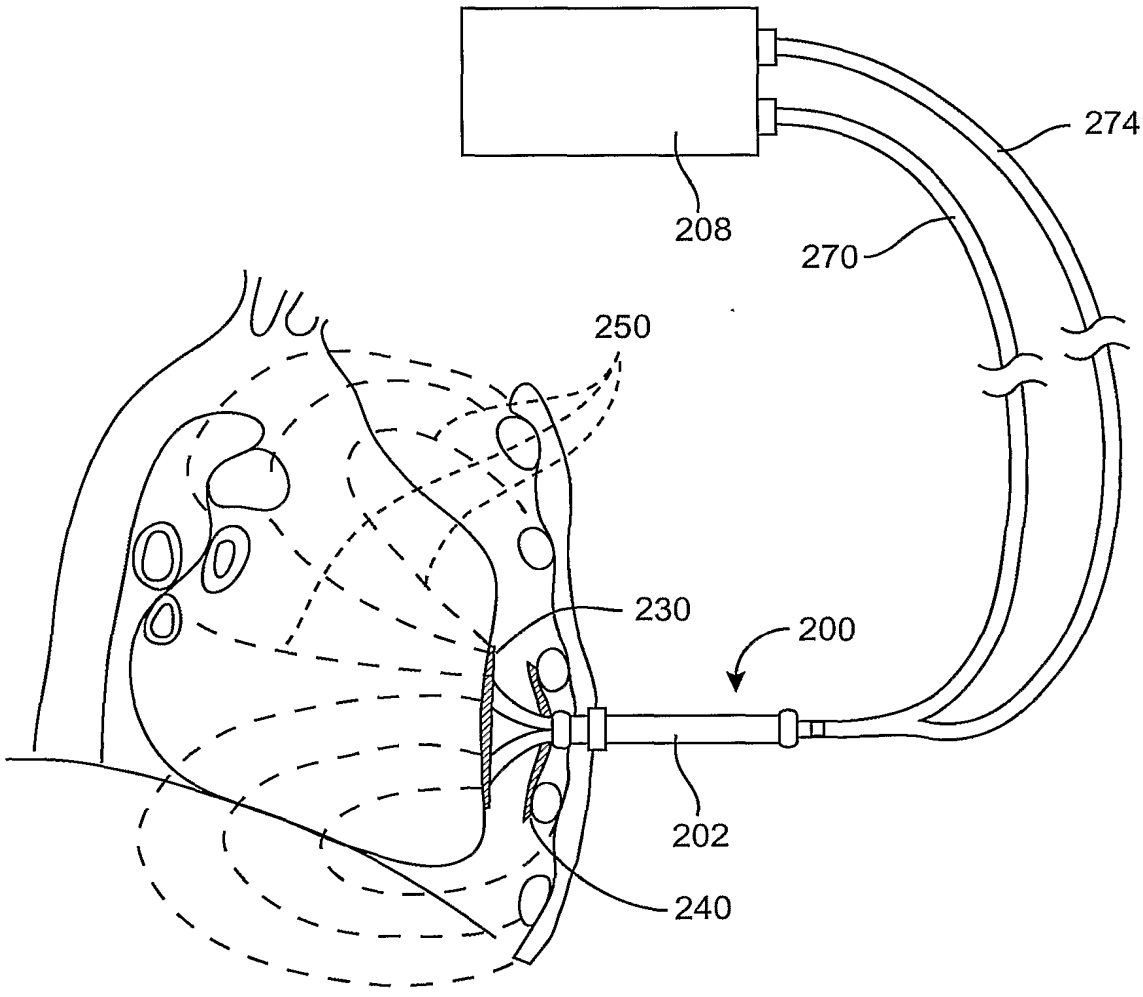


FIG. 7D

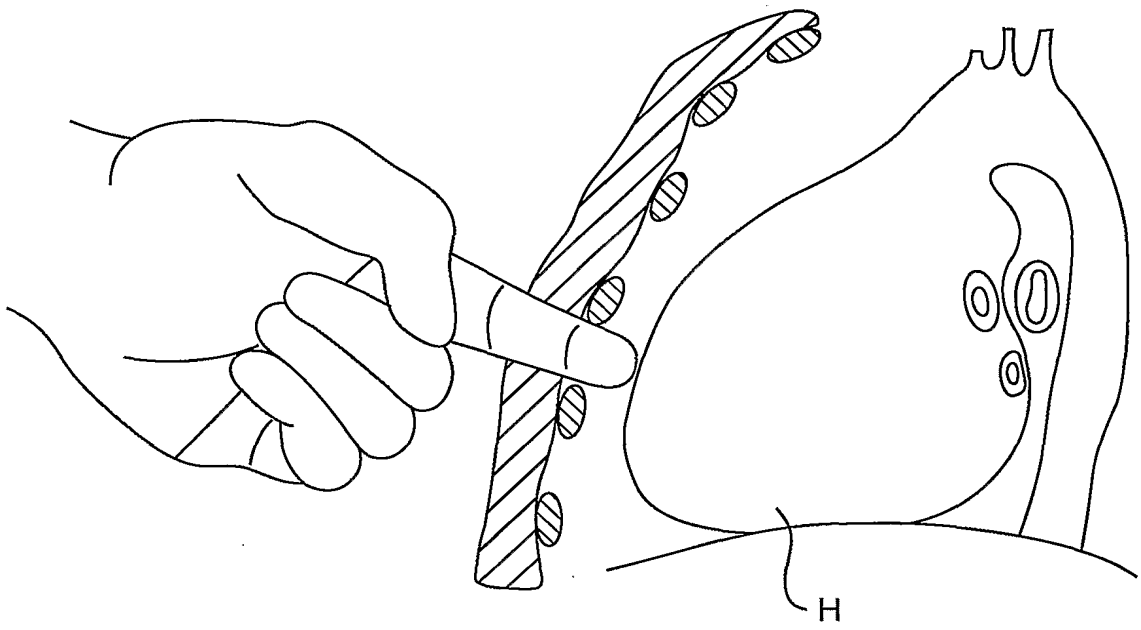


FIG. 7BB

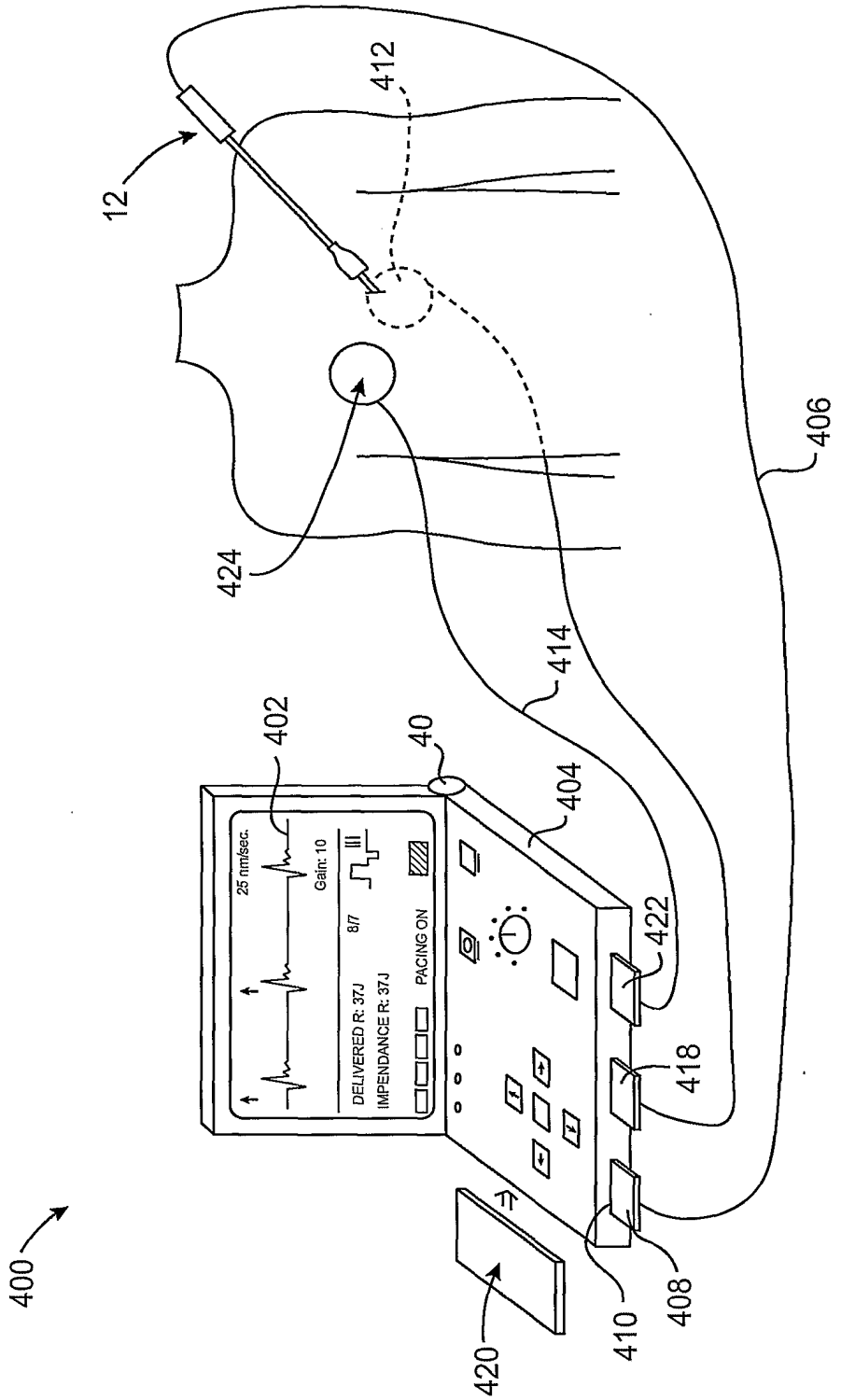

400
12
412
424
406
414
402
40
404
422
418
408
410
420
25 mm/sec.
Gain: 10
8/7
DELIVERED R: 37J
IMPENDANCE R: 37J
PACING ON

FIG. 8

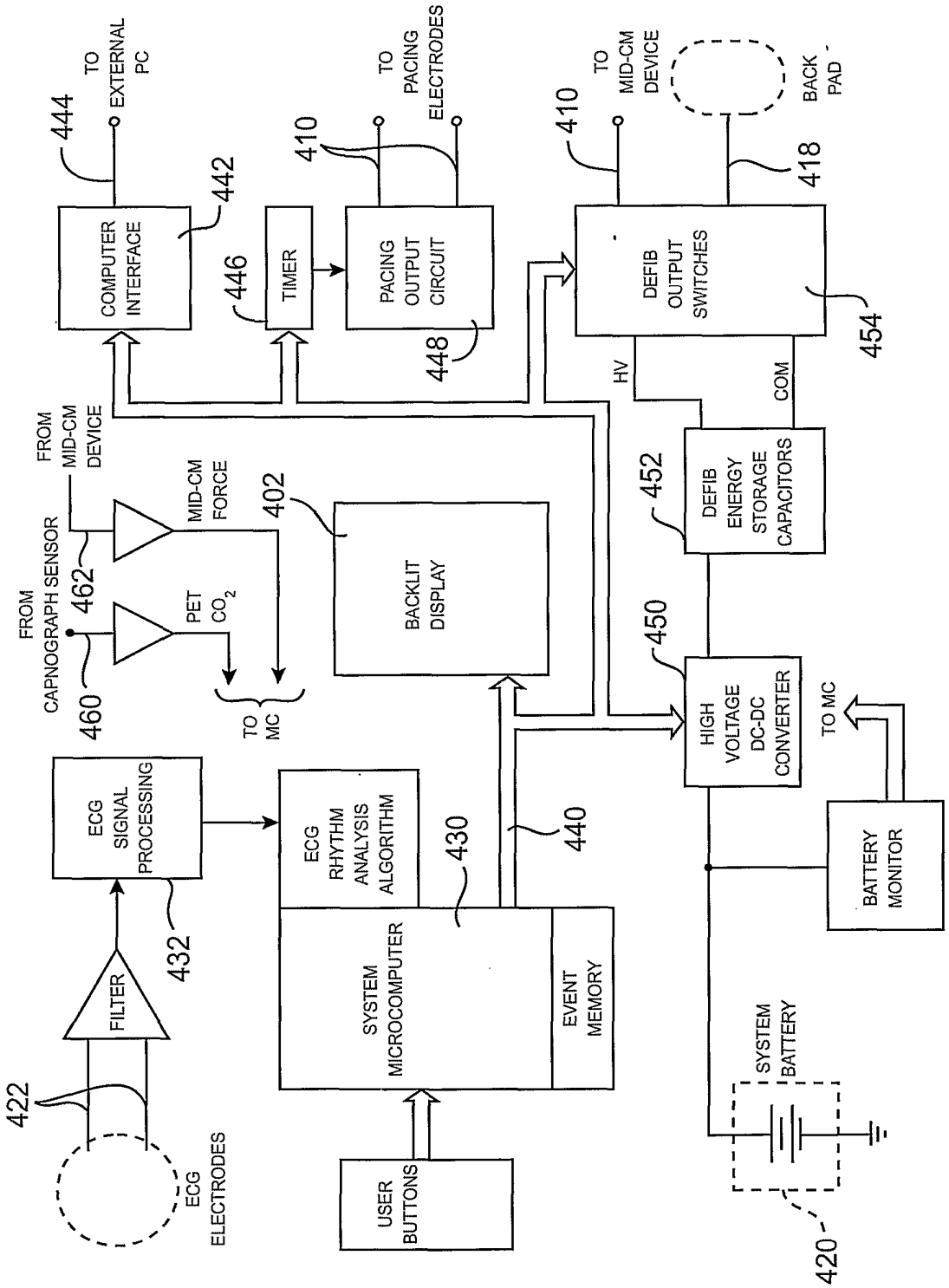

TO EXTERNAL PC
444
COMPUTER INTERFACE
442
TIMER
446
TO PACING ELECTRODES
410
PACING OUTPUT CIRCUIT
448
TO MID-CM DEVICE
410
BACK PAD
418
DEFIB OUTPUT SWITCHES
454
HV
COM
FROM MID-CM DEVICE
MID-CM FORCE
402
BACKLIT DISPLAY
DEFIB ENERGY STORAGE CAPACITORS
452
FROM CAPNOGRAPH SENSOR
462
PET CO_2
460
TO MC
HIGH VOLTAGE DC-DC CONVERTER
450
TO MC
ECG SIGNAL PROCESSING
ECG RHYTHM ANALYSIS ALGORITHM
430
440
BATTERY MONITOR
FILTER
432
SYSTEM MICROCOMPUTER
EVENT MEMORY
422
ECG ELECTRODES
USER BUTTONS
SYSTEM BATTERY
420

FIG. 9

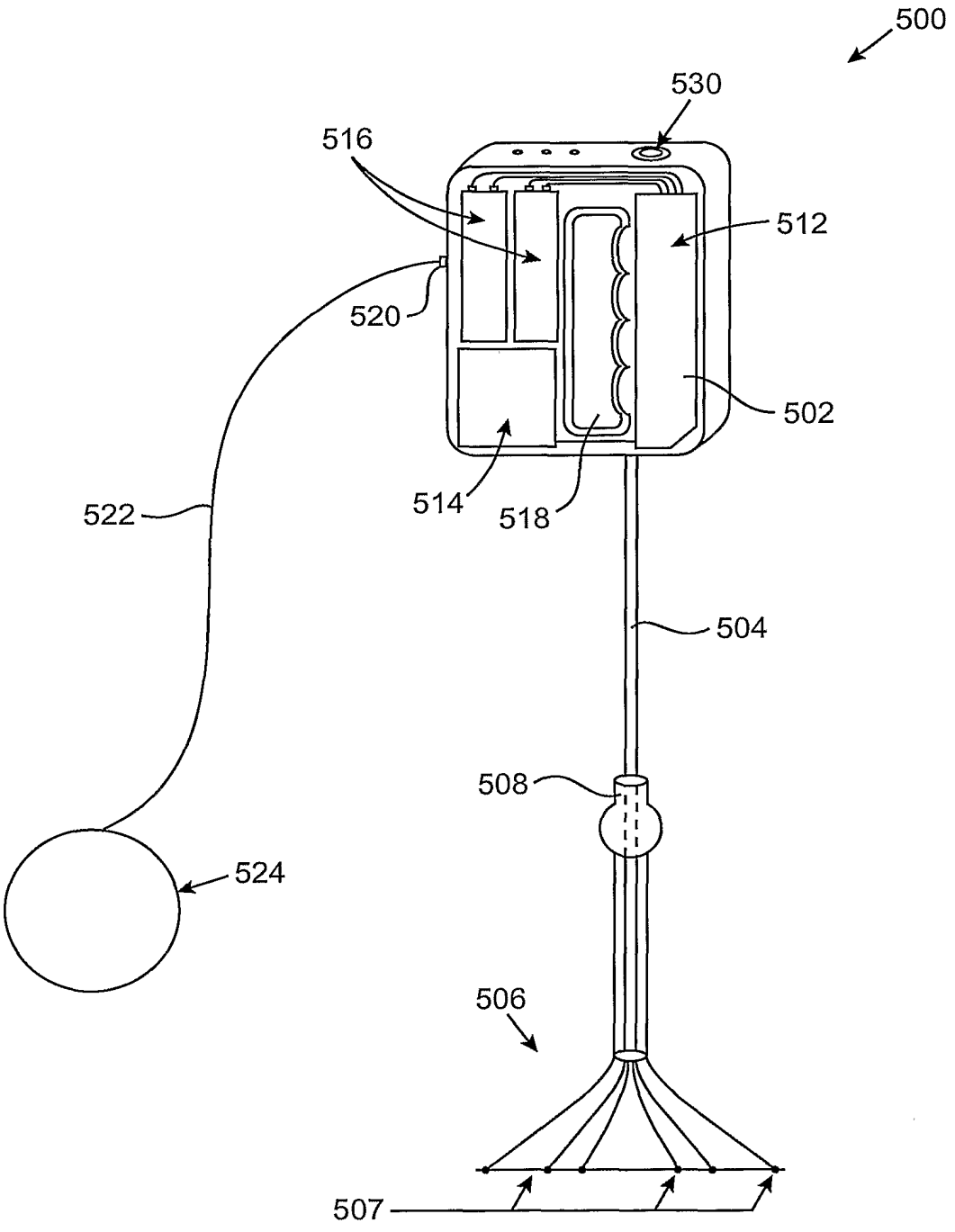


FIG. 10

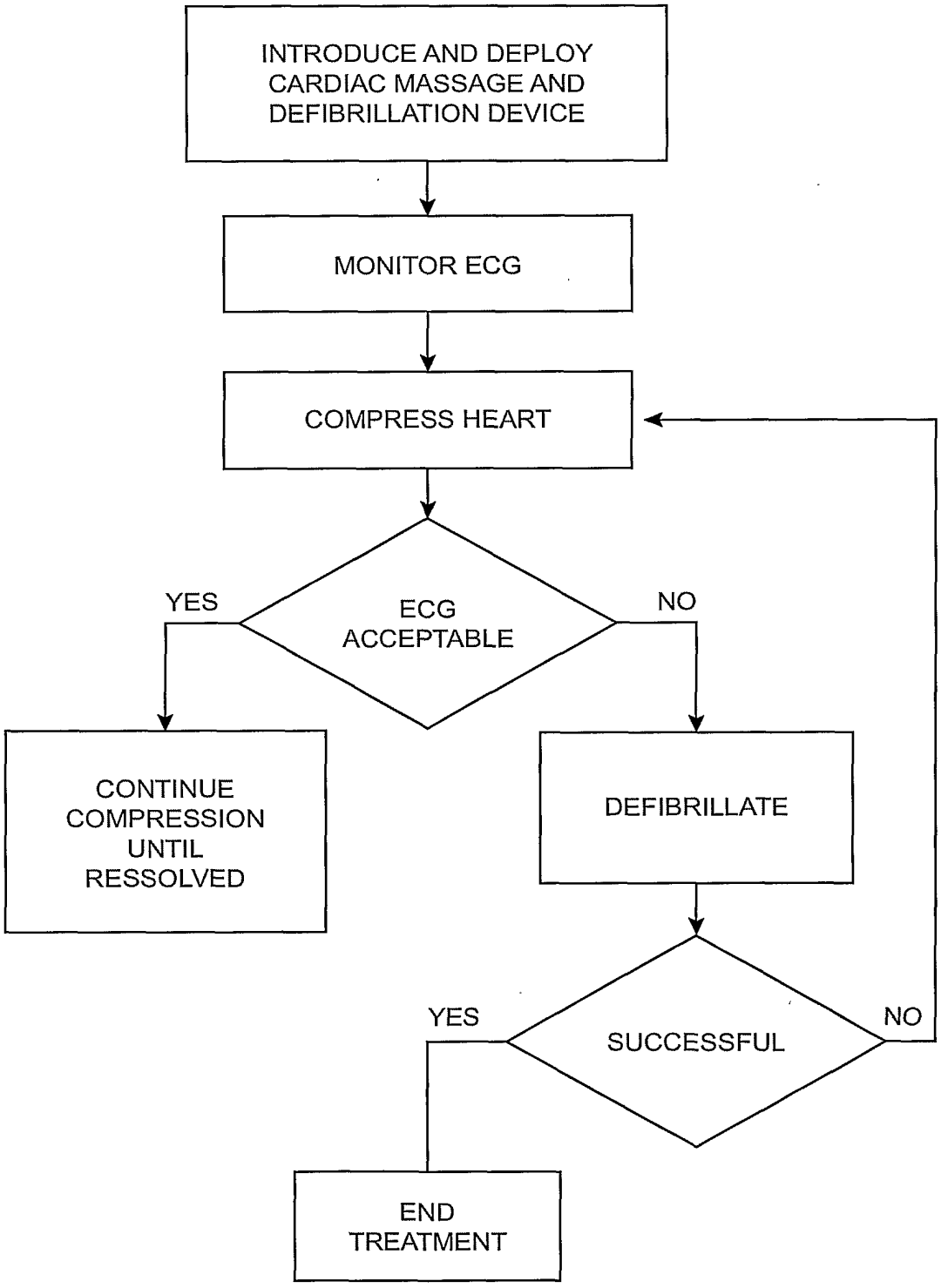

INTRODUCE AND DEPLOY CARDIAC MASSAGE AND DEFIBRILLATION DEVICE
MONITOR ECG
COMPRESS HEART
ECG ACCEPTABLE
YES
NO
CONTINUE COMPRESSION UNTIL RESSOLVED
DEFIBRILLATE
SUCCESSFUL
YES
NO
END TREATMENT

FIG. 11A

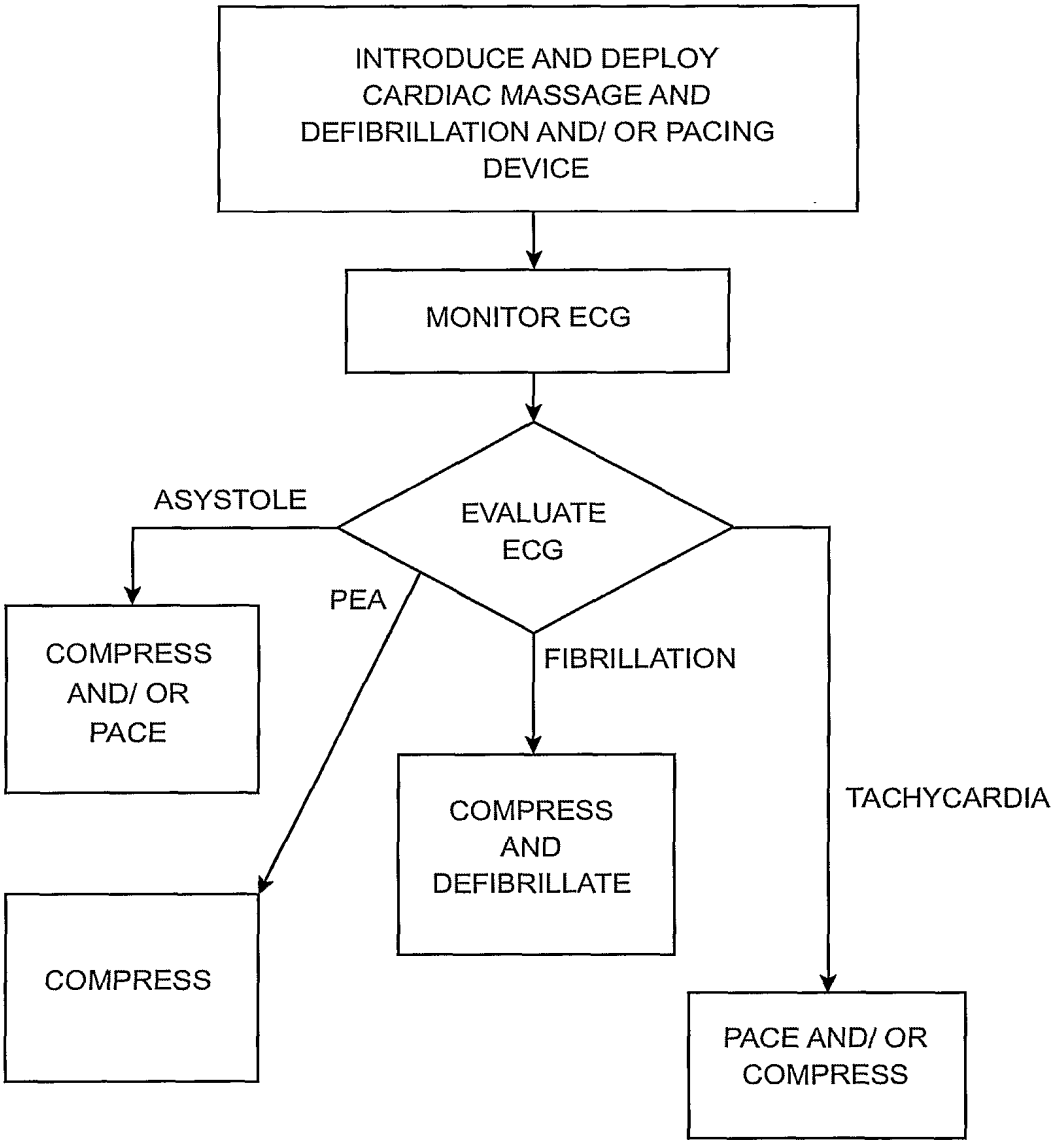

INTRODUCE AND DEPLOY CARDIAC MASSAGE AND DEFIBRILLATION AND/ OR PACING DEVICE
MONITOR ECG
EVALUATE ECG
ASYSTOLE
PEA
FIBRILLATION
TACHYCARDIA
COMPRESS AND/ OR PACE
COMPRESS
COMPRESS AND DEFIBRILLATE
PACE AND/ OR COMPRESS

FIG. 11B

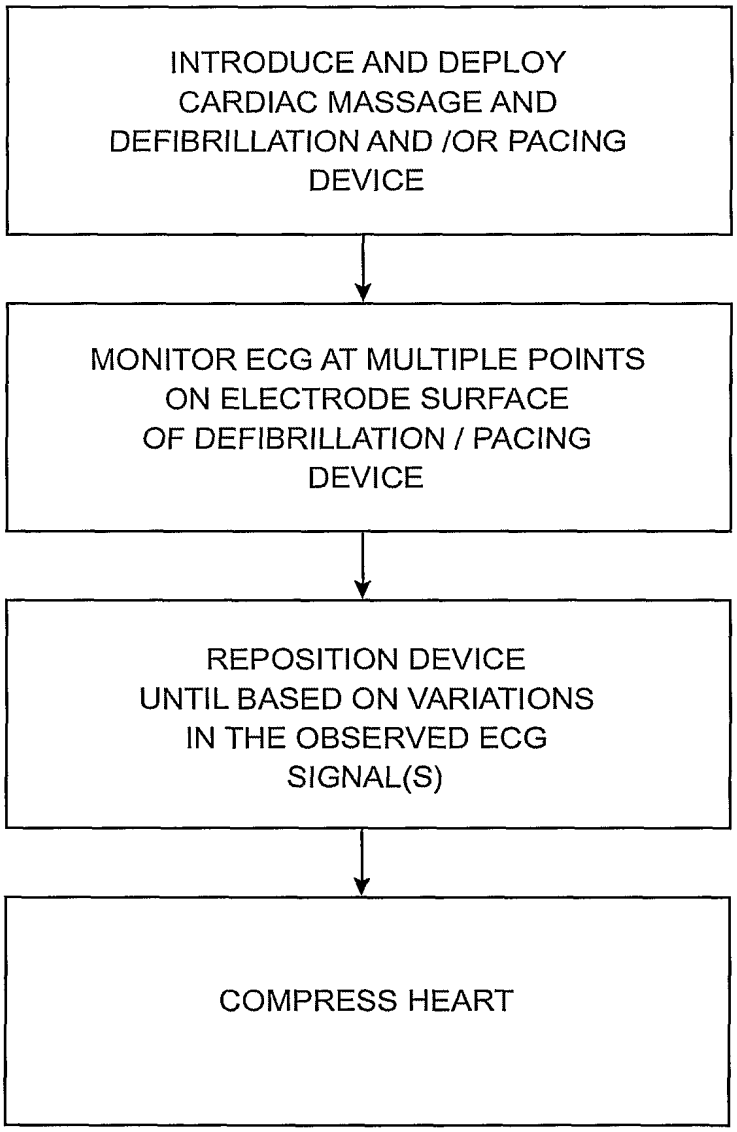

INTRODUCE AND DEPLOY CARDIAC MASSAGE AND DEFIBRILLATION AND /OR PACING DEVICE
MONITOR ECG AT MULTIPLE POINTS ON ELECTRODE SURFACE OF DEFIBRILLATION / PACING DEVICE
REPOSITION DEVICE UNTIL BASED ON VARIATIONS IN THE OBSERVED ECG SIGNAL(S)
COMPRESS HEART

FIG. 11C

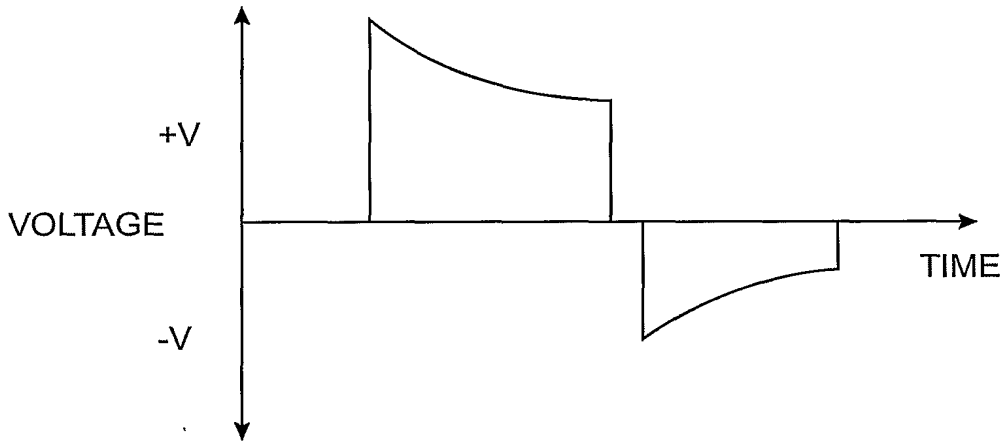


FIG. 12A

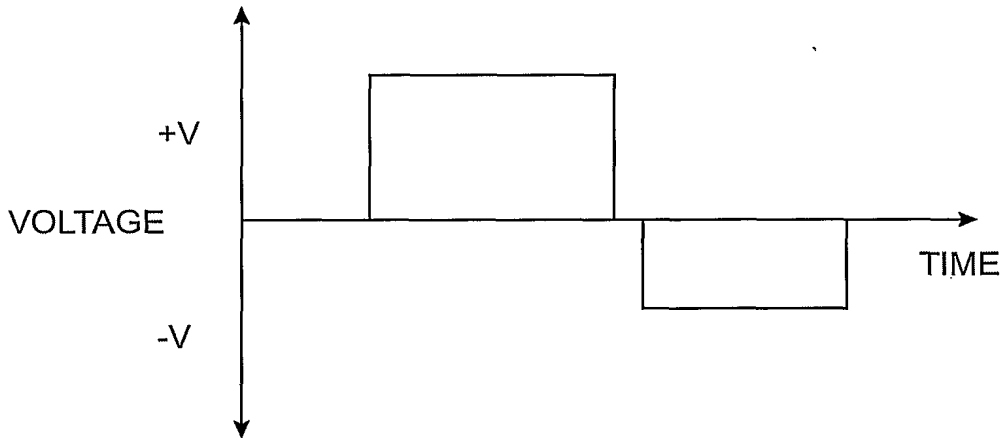


FIG. 12B

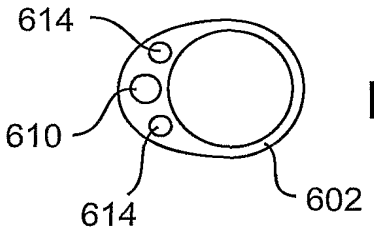


FIG. 13A

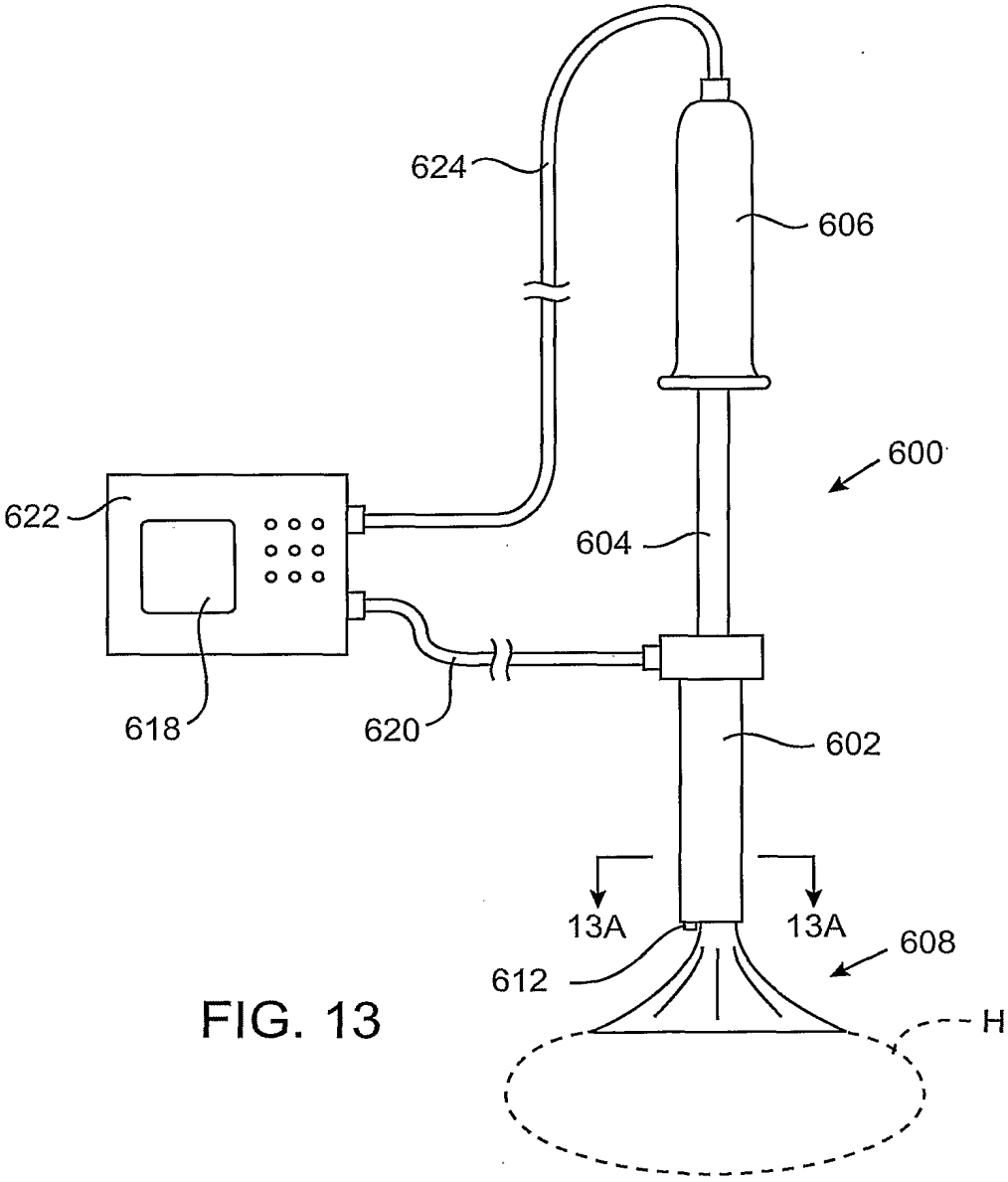


FIG. 13

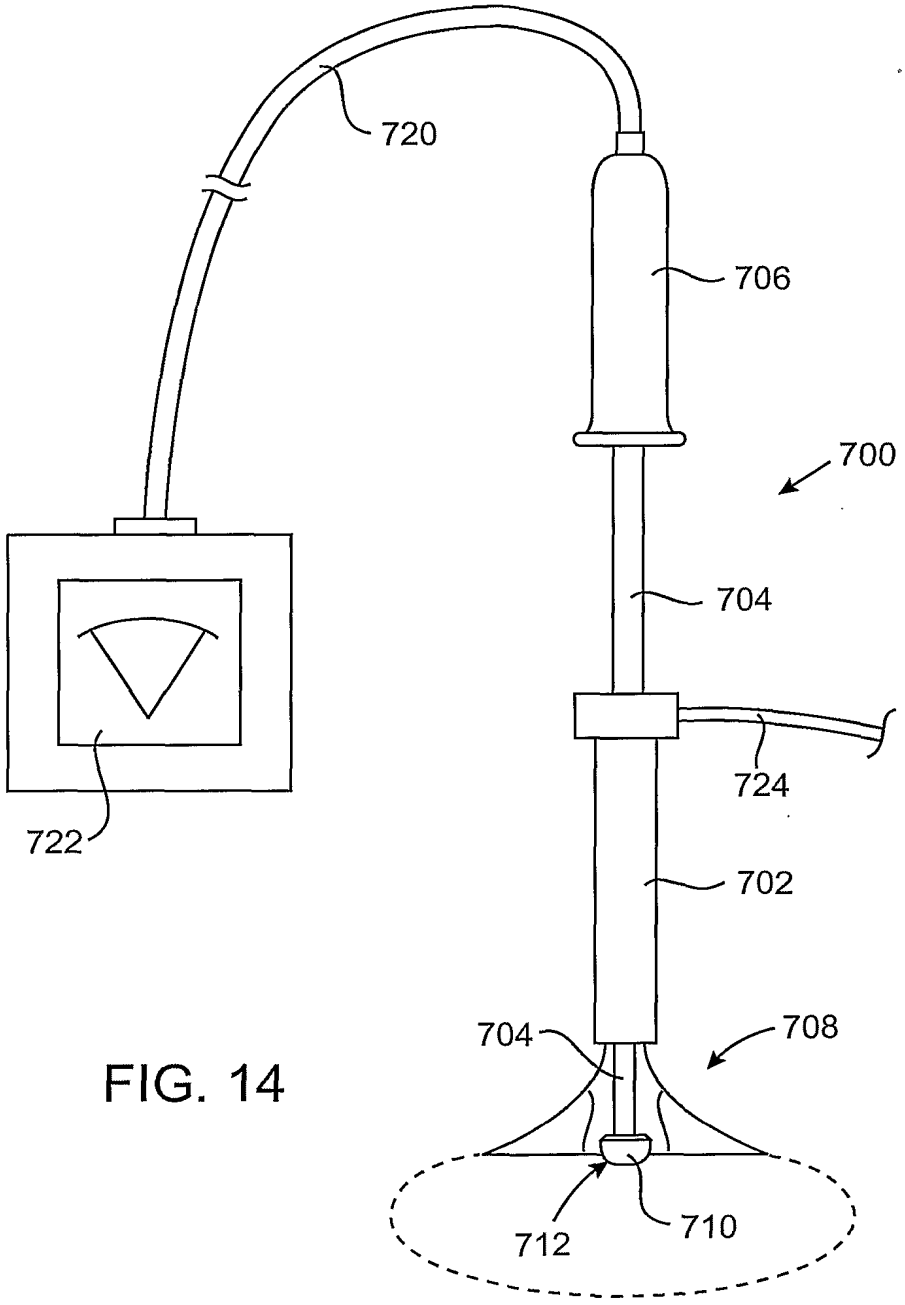


FIG. 14

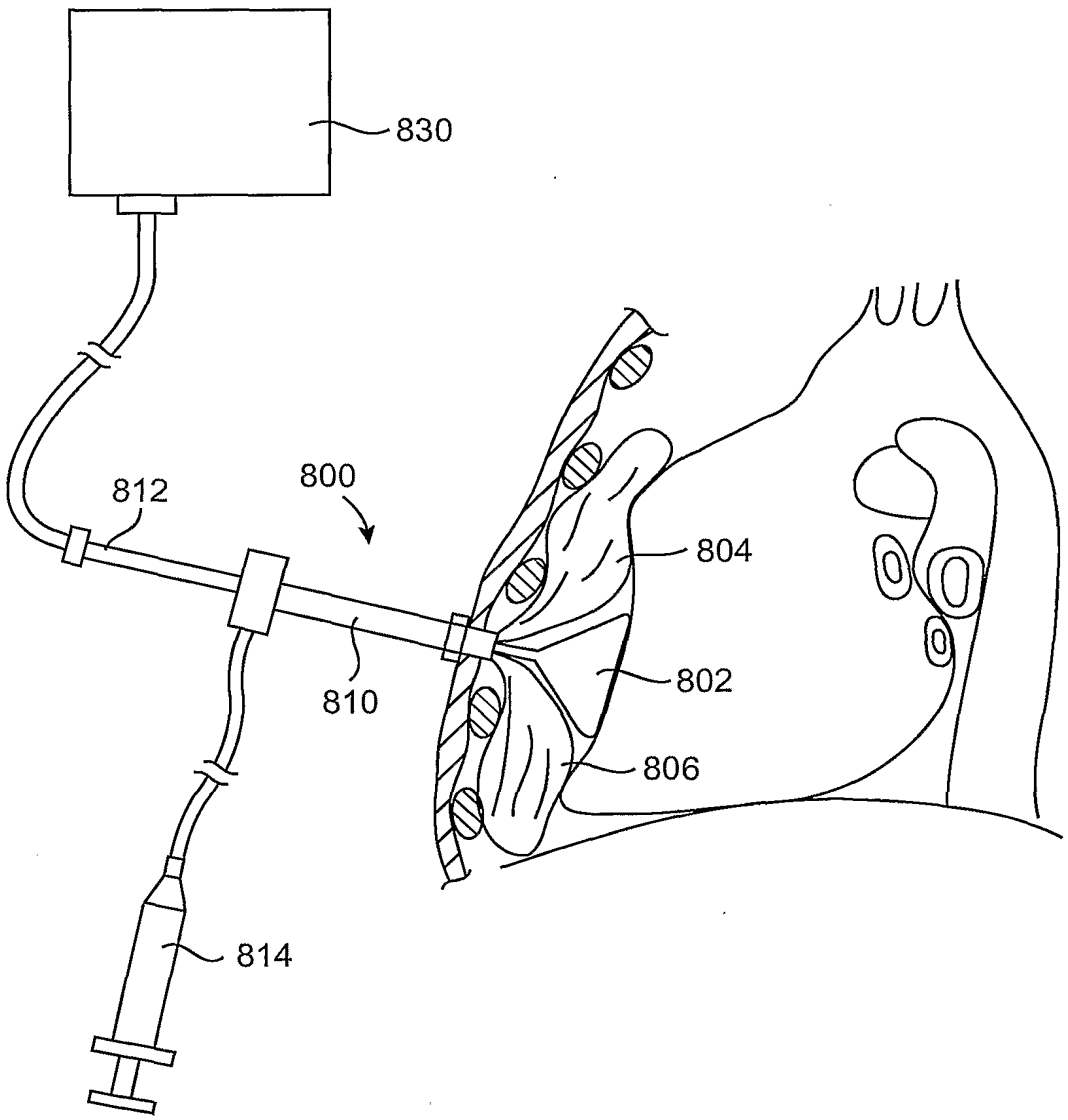


FIG. 15

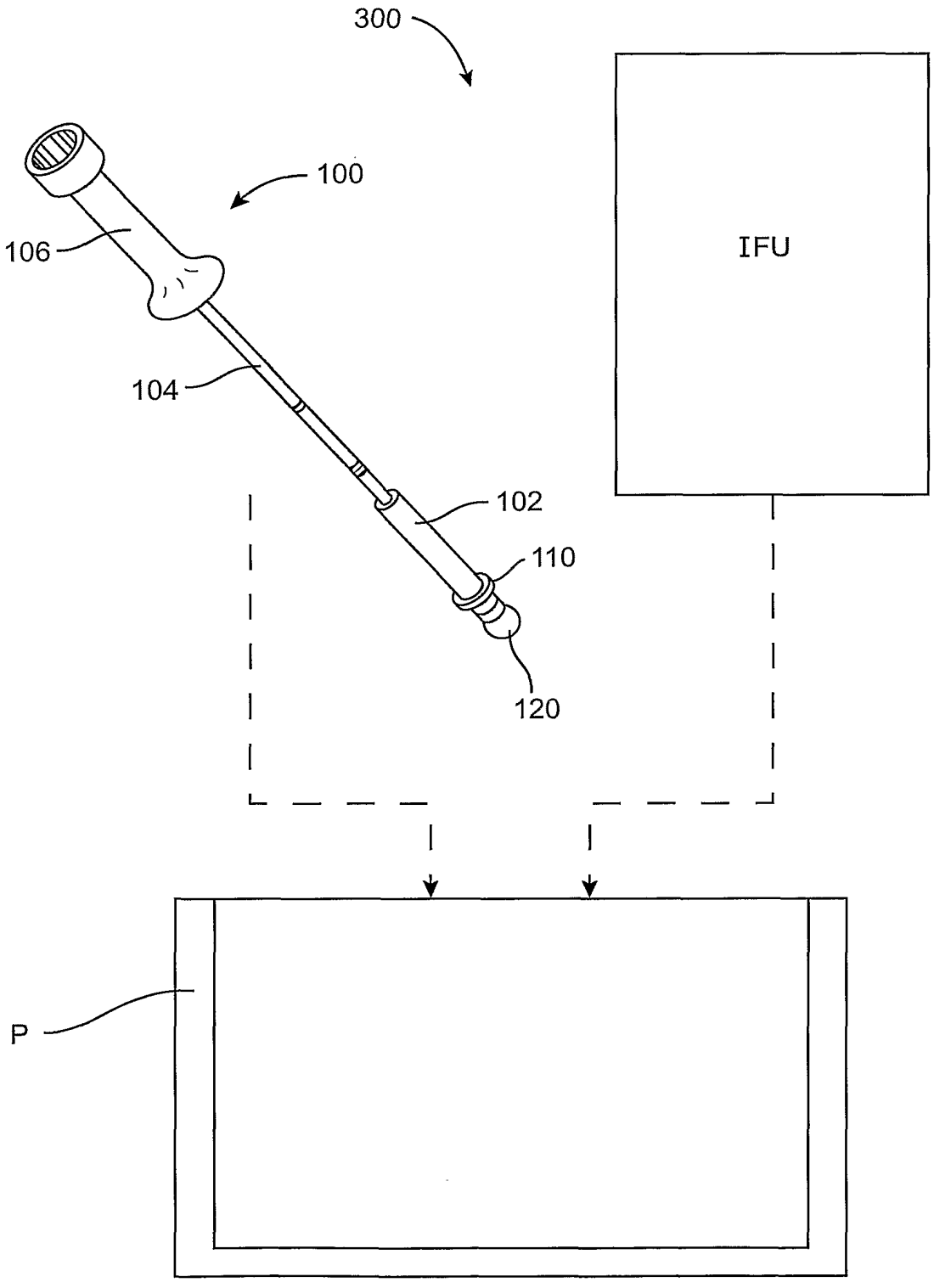


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/03810

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61N 1/39
US CL :607/3, 5, 8

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/3, 5, 8, 129; 600/16, 17; 606/191, 194; 601/15, 41, 43

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/05289 A (Ryan) 12 FEBRUARY 1998, SEE ENTIRE DOCUMENT	1-33, 35-50, 58-64, 67, 68
X	US 5,800,334 A (WILK) 1 SEPTEMBER 1998, SEE ENTIRE DOCUMENT	1-33, 35-50, 58-64, 67, 68

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 26 APRIL 2001	Date of mailing of the international search report 13 JUN 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GEORGE EVANISKO Telephone No. (703) 308-2612

Form PCT/ISA/210 (second sheet) (July 1998)★